Nos. 2015-1672, -1673, -1674, -1712

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NUVASIVE, INC.,

Appellant,

v.

MEDTRONIC, INC.,

Cross-Appellant.

Appeals from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in Nos. IPR2013-00507 and IPR2013-00508

NUVASIVE'S OPENING BRIEF

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August 26, 2015

U.S. Patent No. 8,187,334, Claim 1 (A64-65)

1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:

an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and half times greater than said maximum lateral width;

at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and

at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

CERTIFICATE OF INTEREST

Counsel for NuVasive, Inc. certifies the following:

1. The full name of every party represented by me is: NuVasive, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: None.

4. The names of all law firms and the partners and associates that have appeared for the party in the lower trial court or agency or are expected to appear for the party in this Court are:

Michael T. Rosato, Paul D. Tripodi, II, Richard L. Torczon, Andrew S. Brown, and Grace J. Pak of Wilson Sonsini Goodrich & Rosati.

Stephen R. Schaefer, Michael Hawkins, Stuart Nelson, and Michael A. Amon of Fish & Richardson.

August 26, 2015

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RELATED CASES

The captioned cases are four consolidated appeals from two *inter partes* reviews ("IPRs"), IPR2013-00507 and IPR2013-00508, of U.S. Patent No. 8,187,334 ("the '334 patent") before the United States Patent and Trademark Office, Patent Trial and Appeal Board ("the Board") with Medtronic, Inc. as Petitioner and NuVasive, Inc. as Patent Owner. No prior appeal from these IPRs was previously before this Court or any other court.

This appeal is related to one other appeal pending in this Court. No. 15-1670 is an appeal from an IPR of U.S. Patent No. 8,361,156 ("the '156 patent"). The '156 patent is in the same patent family as the '334 patent, and the two patents largely share the same specification. That appeal has been identified by the Court as a companion case to these consolidated appeals, to be assigned to the same merits panel.

The '334 patent has been asserted by NuVasive against Medtronic in *Warsaw Orthopedic Inc. v. NuVasive Inc.*, No. 3:12-cv-02738-CAB-MDD (S.D. Cal.). The claims and counterclaims in that case related to the '334 patent are currently stayed pending resolution of the IPRs that are the subject of these appeals.

JURISDICTION

The Board issued its Final Written Decisions in both IPRs on February 11, 2015. A1; A17. Medtronic filed timely notices of appeal on April 14, 2015 under 35 U.S.C. §§ 141(c) and 142; NuVasive filed timely notices of appeal on April 15, 2015 under 35 U.S.C. §§ 141(c) and 142. This Court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

ISSUES ON APPEAL

Whether the Board's ruling that claims 1-5, 10, 11, 14-17, and 19-28 are obvious should be reversed where:

1. The Board erred by crafting new grounds of unpatentability in its Final Written Decisions to which NuVasive had no opportunity to respond and to which the Board explicitly told NuVasive that it could not respond;

2. The Board substituted its own speculation for record evidence in finding that the prior art taught the claimed dimensions; and

3. The Board further erred in failing to identify a reason to modify the prior art to arrive at the claimed invention, especially where the prior art did not teach the claimed narrower dimensions in the context of a single, self-sufficient implant and there was no record evidence regarding fundamental aspects of such a modification, including the state of the art of modular implants or even whether the

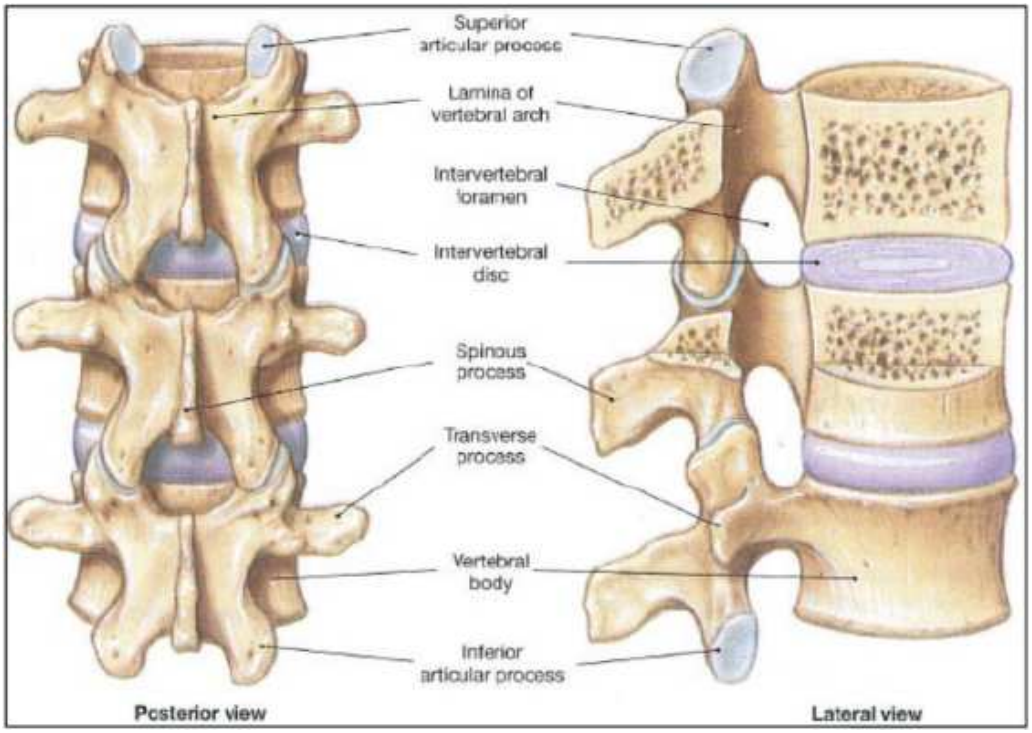
primary references would have been suitable for use as modular members in a modular implant.

STATEMENT OF THE CASE

This appeal is from two IPRs of the ’334 patent owned by NuVasive. NuVasive appeals the Board’s rulings that claims 1-5, 10, 11, 14-17, and 19-28 of the ’334 patent are unpatentable as obvious in view of the cited prior art.

I. Technology Background

As depicted below, the human spine comprises a series of stacked vertebrae separated by intervertebral discs. A4944-45 ¶ 28.



The left image shows a view of the spine from the back, while the right image shows a view of the spine from the side. Spinal fusion surgery is most commonly

performed to correct chronic back pain caused by diseased or damaged intervertebral discs. A59, 1:27-29; A4947 ¶ 33. At a most basic level, spinal fusion surgery involves removing some or all of a diseased or damaged disc and inserting a spinal implant in the resulting disc space. A59, 1:29-32. The inserted implant restores the height between adjacent vertebral bodies and is designed to induce bone growth between the vertebrae. *Id.* at 1:32-36; A4946 ¶ 31

Spinal fusion implants are created through a rigorous process of research, testing, and analysis. A4949-51 ¶¶ 39-41. The size of a spinal fusion implant is central both to the intended insertion path of the implant and to the performance of the implant. *Id.* For example, spinal fusion implants are sized to allow them to be inserted while avoiding contact with critical anatomy near a given insertion path, such as the spinal cord and large blood vessels, to avoid paralyzing or killing the patient. *See, e.g.*, A4943-45 ¶¶ 26-28; A4947-48 ¶¶ 34-35. As far as stability, larger implants are better able to structurally support and properly space adjacent vertebrae. A4951 ¶ 41. It is important that a spinal fusion implant not only fit, but also that it can be positioned, supports the heavy load placed on the spine, aligns the spine, stays in place, and allows the spine to fuse and heal. *Id.* A spinal fusion implant must meet all of these requirements to be useful for patient treatment. *Id.*

Even slight changes to the design of a spinal fusion implant, particularly the dimensions, can have a dramatic effect on the functionality of the implant from a

clinical perspective. A4950-51 ¶¶ 40-41. Small design changes can and do have unintended effects that negatively affect the performance of a spinal fusion implant. A4950-51 ¶ 40. A small change in the size of an implant can mean the difference between an implant that alleviates pain, and one that causes significant additional problems for the patient. *Id.* Accordingly, determining appropriate implant dimensions can be a difficult process, especially when attempting to design implants for relatively new spinal fusion procedures that have no conventional implant designs to emulate. *See, e.g.*, A4955-57 ¶¶ 48-52.

II. ’334 Patent

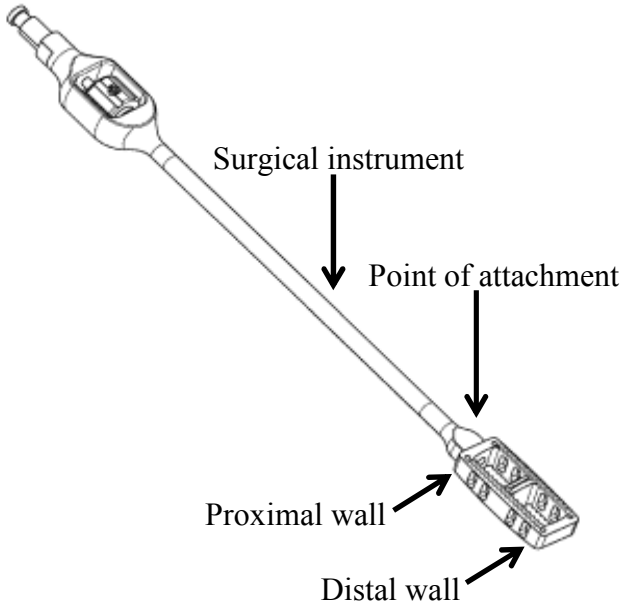
The claims of the ’334 patent are directed to a spinal fusion implant with dimensions that make it particularly suited for insertion into an intervertebral disc space using a lateral, trans-psoas approach. Such an approach was uncommon prior to the invention of the ’334 patent, and so implants designed for a lateral, trans-psoas approach were uncommon. A4955 ¶ 48. In 2003, NuVasive pioneered the surgical procedure that made the lateral, trans-psoas approach safe. NuVasive calls this innovation “eXtreme Lateral Interbody Fusion,” or “XLIF,” and surgeons who use that procedure use NuVasive implants that are covered by the ’334 patent.

Before NuVasive’s development of the XLIF procedure, almost all spinal fusion surgeries used either an anterior or posterior approach to the spine. A4955 ¶ 48. That is, they involved inserting a spinal implant through the front or back of

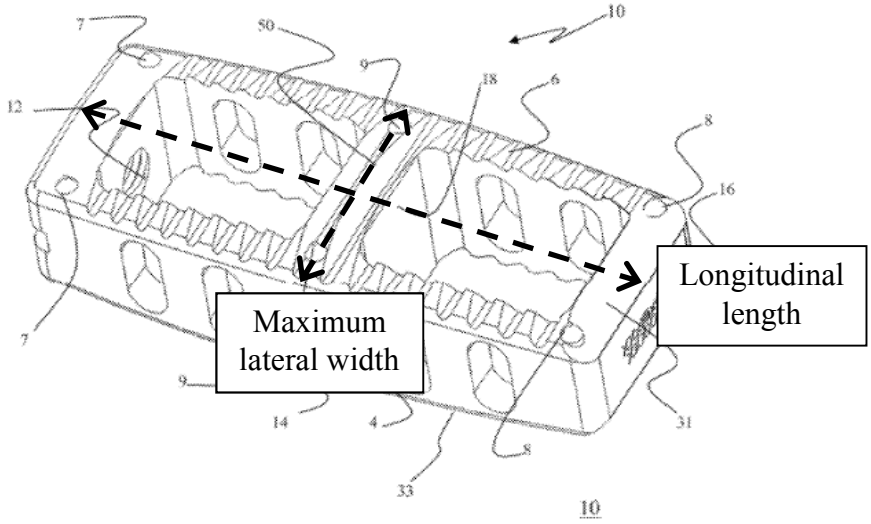
the patient, respectively. In contrast, a lateral approach to the spine involves inserting a spinal implant through the side of the patient. More particularly, a trans-psoas approach is a lateral approach that goes directly through the psoas muscle, which runs along the side of the lumbar (lower) portion of the spine and contains large bundles of motor nerve roots that exit the spinal cord to innervate the muscles of the legs and lower extremities. A4943 ¶ 26; A4955 ¶49. Historically, surgeons avoided using such an approach for fear of damaging these large motor nerve roots while penetrating the psoas muscle. *Id.*

The spinal fusion implants claimed in the ’334 patent are designed for insertion using such a lateral trans-psoas approach, and in particular, have dimensions suitable for such an approach. A0061, 5:29-31.

The ’334 patent describes the unique dimensions of the claimed implant using some specialized terminology. Proximal and distal refer to near to and away from, respectively, the point of attachment of the surgical instrument used to insert the implant, as shown in the below annotated Figure 1 of the ’334 patent.



Claim 1, from which all of the challenged claims depend, requires, among other things, that the implant have a length from proximal wall to distal wall that is greater than 40 mm. It also requires that the implant be narrow relative to its length, with a length at least two and a half times greater than its greatest width.



Accordingly, claim 1 of the ’334 patent reads:

1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:

an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;

wherein ***said implant has a longitudinal length greater than 40 mm*** extending from a proximal end of said proximal wall to a distal end of said distal wall;

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein ***said longitudinal length is at least two and half times greater than said maximum lateral width***;

at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture

> having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and
>
> at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region. A64-65 (emphasis added).

III. Cited References

Medtronic asserted five references as prior art that are relevant to the issues in this appeal. None of these five references, alone or in any reasonable combination, disclose an implant that is greater than 40 mm long and that also has a length greater than two-and-a-half times its width, nor do they suggest any reason to combine or modify their teachings to arrive at such an implant. Instead, the prior art disclosed either shorter implants (*i.e.*, Frey, SVS-PR, and Telamon) or implants that were both long and wide (*i.e.*, Michelson).

A. Frey

U.S. Patent Application Publication No. 2002/0165550 to Frey ("Frey") is entitled "Devices and Techniques for a Posterior Lateral Disc Space Approach." A699. Frey discloses a banana, or boomerang, style implant. A758, ¶ 140.

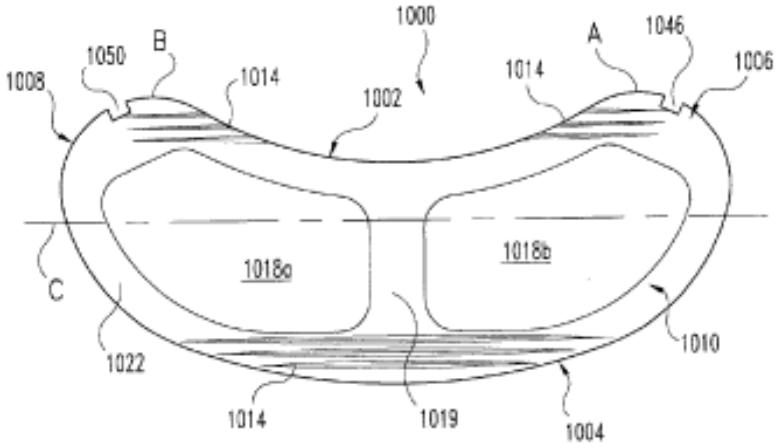


Fig. 55

A740. Boomerang implants are sized and shaped to be positioned and fit in a particular portion of the disc space (which would typically be an anterior portion in the lumbar spine or a posterior portion in the thoracic spine), and the curvature helps ensure an optimum fit. A760-61¶ ¶ 151, 159. Such a shape is also optimally adapted for use in insertion procedures that require turning the implant during the procedure, such as the posteriolateral approach disclosed in Frey. A758-61 ¶¶ 140, 150, 159.

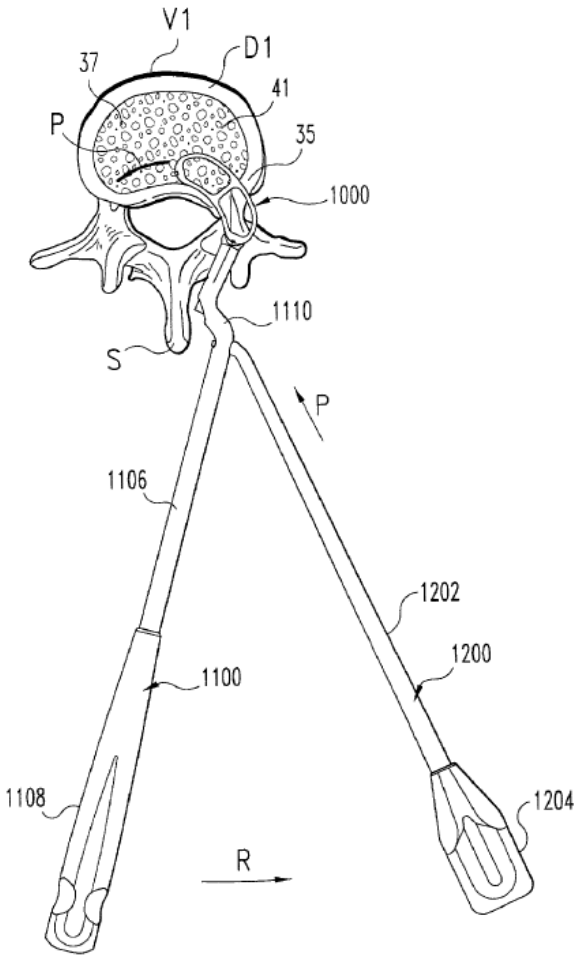


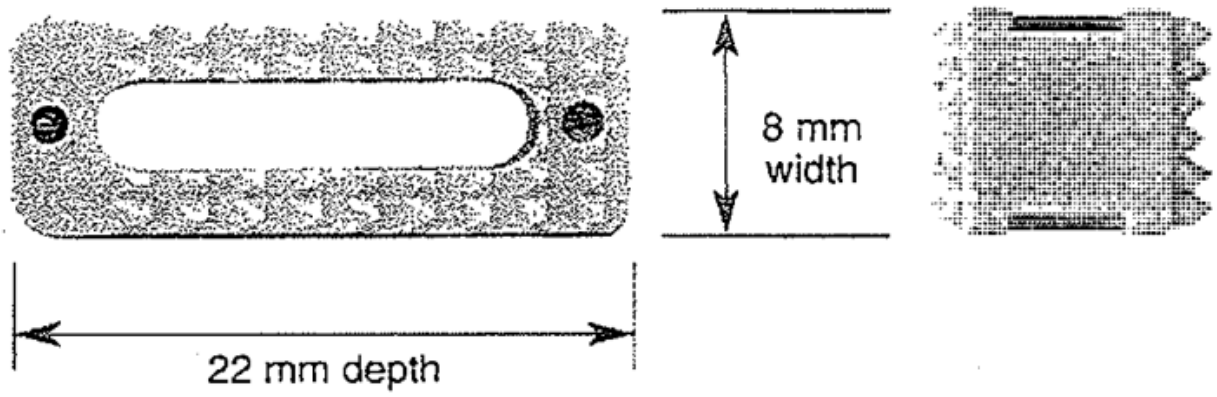
Fig. 53

A739. Frey does not disclose the dimensions of the implant, and the commercial embodiments of Frey were less than 40 mm in length. A4448.

B. SVS-PR Brochure

The Synthes Vertebral Spacer-PR brochure ("SVS-PR brochure") is a sales brochure for a spinal fusion implant designed to be inserted using a posterior

approach. A6422. The disclosed implant has a length[1] of 22 mm and a width of 8 mm. *Id.* The SVS-PR brochure does not disclose any implant with a length greater than 40 mm.



C. Telamon Brochure

The Telamon Verte-Stack PEEK Vertebral Body Spacer brochure ("Telamon brochure") is a sales brochure for a Medtronic spinal fusion implant designed to be inserted using a posterior approach. A6424-25. The Telamon brochure discloses implants with dimensions ranging from a width of 8 mm and length of 22 mm to a width of 14 mm and a length of 26 mm. A6425. The Telamon brochure does not disclose an implant with a length greater than 40 mm.

[1] The brochure refers to the implant's longest dimension as its "depth," because the implant is designed to be inserted (and placed) in the spine from a posterior approach, rather than a lateral approach. In this case, the "depth" of the implant aligns with the depth of the vertebrae.

D. Telamon Implantation Guide

The Telamon Posterior Impacted Fusion Devices guide ("Telamon guide") is a guide that describes a procedure for implanting the Telamon spinal fusion implant using a posterior approach. A6426. The Telamon guide does not disclose any particular dimensions. *Id.*

E. Michelson

U.S. 5,860,973 to Michelson ("Michelson") discloses different kinds of translateral spinal fusion implants, all of which are oversized. A788-89, 5:44-45, 7:31-33, 7:46-47. For example, Michelson discloses cylindrical dowel-style implants with different surface finishes. *See* A778-83. Michelson also discloses more rectangular implants that are "inserted in the disc space D between the adjacent vertebrae of the spine and not into a cylindrical bore." A790, 10:8-12.

In contrast to the claimed invention, which is a long, narrow implant, Michelson proposes implants that are oversized in both their length and width in order to maximize the surface area of contact with the vertebrae:

> An ***oversized*** spinal implant for translateral insertion into the disc space between two vertebrae [*sic*, with] ***a length that is greater than one half of the transverse width of the vertebrae and is greater than the depth of the vertebrae***. The translateral implant of the

> present invention has a height that is greater than the height of the disc space between two adjacent vertebrae so as to engage both of the vertebrae. The ***width of the implant need be only slightly less than the depth of the vertebrae themselves***. The translateral spinal fusion implant of the present invention has ***more surface area*** of contact and thus permits ***greater stability*** so as to withstand torque, and in the case of a threaded implant, increases the depth which any threads are able to penetrate the vertebrae. A777, abstract (emphases added).

The Detailed Description of Michelson further describes and touts the importance of implants being both long and ***wide***, claiming for example: "[a]s a result of the large length and ***diameter*** of the implant 100a, a large surface area of contact between the implant 100a and the vertebrae V1 is possible creating a highly stable construct." A788, 6:51-54 (emphasis added). Michelson explains that the proposed implants have "a much greater surface area of contact with the vertebra V1 than was previously possible." A788, 6:54-56. In contrast, the claimed implant has a narrow width that does not seek to maximize the surface contact area with the adjacent vertebrae.

Michelson also proposes dimensions in two categories that include specific length and width combinations that were thought appropriate and preferred for laterally inserted implants—a first category of dimensions specifically for the "lumbar" spinal fusion implants (in the lower segment of the spine), and an entirely different, second category of dimensions specifically for "thoracic" spinal

fusion implants (in the middle segment of the spine). In the first category, the dowel implant for use in the ***lumbar*** spine has "an overall length in the range of 35 mm to 50 mm, with 38-44 mm being preferred, and a maximum diameter [width] in the range of 22 mm to 30 mm, with 24-26 mm being preferred." A789, 7:21-27.

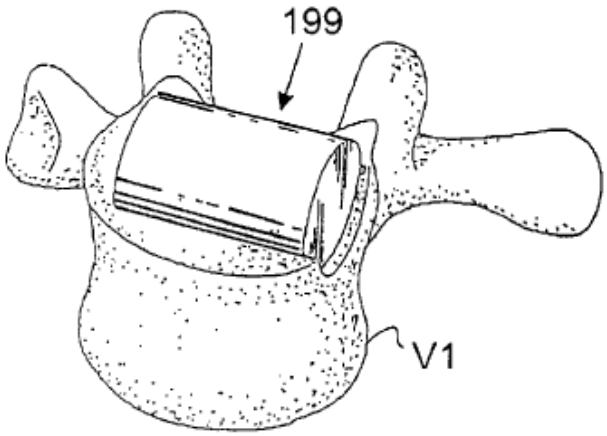


FIG. 7

A780. The rectangular ***lumbar*** implant has "a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length." A790, 10:41-46.

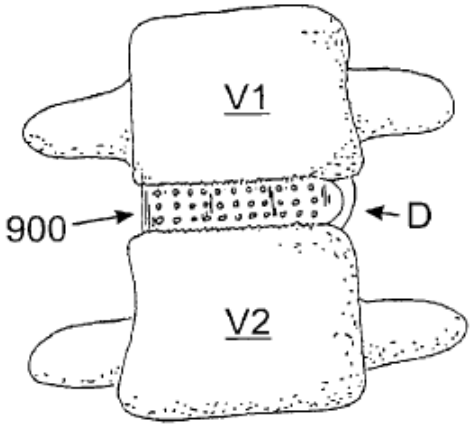


FIG. 17

A784. Michelson also describes a modular implant comprised of modular members each of which is "similar" to the rectangular lumbar implant, "but has a narrower width such that more than one spinal fusion implant 1000 may be ***combined in a modular fashion for insertion*** within the disc space D between the adjacent vertebrae." A790, 10:51-55; *see also* A791, claim 21 ("The implant of claim 1 which said implant comprises a plurality of modular members, . . .").

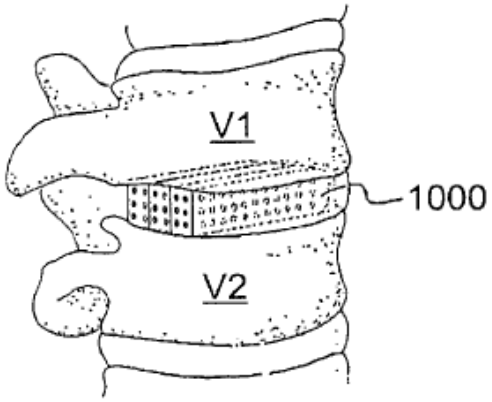


FIG. 19

A784. Michelson does not otherwise disclose the dimensions of the modular members. Michelson also does not suggest that the modular members be used independently or in any way other than as part of a modular implant.

In the second category, the smaller ***thoracic*** dowel implants have "a length in the range of 12-30 mm, and a maximum diameter in the range of 14-26 mm, with the preferred diameter being 20 mm." A789, 7:26-30.

Michelson proposes implants in which the width (or diameter in the case of the dowel designs) is quite large even compared to the largest dimension (the length), thereby providing an implant that is both long and wide to fulfill the

intended purpose of an "oversized" spinal implant. A777, abstract; A788-90, 6:51-54, 7:21-27, 10:41-46; *see also* A4979-80 ¶ 93; A4994 ¶ 111; A5001 ¶ 118. Michelson never proposes that the length dimension of lumbar implants should be used in combination with a much smaller width. *See* A4980-81 ¶ 94; A4993-94 ¶¶ 110, 111. Michelson also does not disclose any implants with a length to width ratio of two-and-a-half to one.

IV. *Inter Partes* Review

Medtronic filed two Petitions requesting IPR of the '334 patent alleging that the challenged claims were unpatentable as obvious over various interrelated combinations of the references. A115; A5707. NuVasive filed Preliminary Responses. A189; A5781. The Board instituted IPR on the grounds listed here.

Claims	Prior Art References
IPR2013-00507	
1-5, 10, 11, 14, 15, and 18-28	Frey and Michelson
IPR2013-00508	
1-5, 10, 11, and 14-28	SVS-PR, Baccelli, and Michelson
1-5, 10, 11, and 14-28	Telamon,[2] Baccelli, and Michelson

[2] Both Medtronic and the Board referred to the Telamon brochure and the Telamon guide collectively as "Telamon" and generally treated the references as a single commercial embodiment, rather than as distinct printed publications. *See, e.g.,* A5713 n.2 ("The Telamon Brochure and the Telamon Guide both describe the same implant. As such, Petitioner is treating their combined disclosure as a single publication.").

For each instituted ground, Medtronic relied on the Frey, SVS-PR, or Telamon references for most elements—for example, the particularly claimed upper and lower surfaces with anti-migration elements, sidewalls and end walls, fusion apertures, and radiopaque markers. Medtronic argued that one of ordinary skill in the art would have been motivated to modify the implants disclosed in those primary references to have a length greater than 40 mm in light of the Michelson reference.

A. Medtronic's Initial Grounds of Unpatentability

In its Petitions, Medtronic proposed initial grounds of unpatentability. In particular, to supply the claimed length of greater than 40 mm, Medtronic cited to an embodiment disclosed in Michelson:

> In the preferred embodiment, the spinal fusion implant 900 has a height in the range of 8 mm to 16 mm, with the preferred height being 10-12 mm; a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length. A790, 10:41-46 (cited in A174 and A5730, A5754).

The embodiment of Michelson cited by Medtronic, however, does not have a length to width ratio of two-and-a-half to one, as specifically required by claim 1 of the '334 patent. The preferred length of 42 mm is not at least two-and-a-half times greater than 26 mm. Indeed, even taking the opposite extremes of the

disclosed ranges, a width of 24 mm and a length of 50 mm, would not result in an implant with a length at least two-and-a-half times greater than its width. So instead, as to the claimed ratio of length to width, Medtronic pointed to the dimensions of the primary references, unmodified in view of Michelson:

> The actual values of angles B3, B4 and B5 as shown in Figure 66 of Frey match the values provided in the Specification of Frey. Therefore, Figure 66 of Frey, or at least the portion [of] Figure 66 that is associated with these angles, is drawn to proportion and reasonably discloses to one skilled in the art that ***the implant disclosed in Frey has a longitudinal length that is at least two and a half times the maximum lateral width***. A139 (citing A762 ¶ 167) (emphasis added).
>
> The SVS-PR Brochure provides that in certain embodiments, ***the SVS-PR has a longitudinal length at least two and a half times [greater] than the maximum lateral width***. A5731 (citing A6422) (emphasis added).
>
> The Telamon Brochure provides that ***the Telamon has a 10mm width, and may have a length of 26mm***. A5754 (citing A6425) (emphasis added).

In other words, Medtronic treated obviousness as a matter of spotting each claim requirement in the prior art, regardless of how those requirements would operate as a whole, even where those requirements were as plainly dependent on one another as with the length, on one hand, and the length relative to width, on the

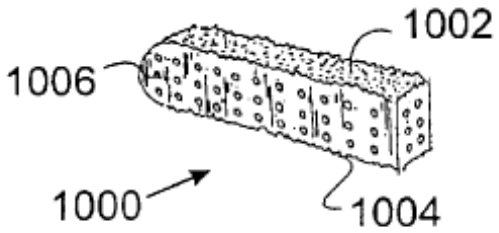
other. With respect to the length requirement, Medtronic argued that it would "have been obvious to follow the teachings of Michelson for a lateral or anterolateral implant and related surgical technique, ***including the specific dimensions disclosed by Michelson*** for an implant inserted laterally or antero-laterally." *E.g.*, A172 (emphasis added). But Medtronic's Petition did not address, nor did Medtronic appreciate, how modifying the primary references to incorporate the "specific dimensions" disclosed by Michelson (*i.e.*, both the lengths and the widths disclosed by Michelson) would affect the requirement that the claimed implant have a length at least two-and-a-half times greater than its width.

Accordingly, in its Patent Owner Responses, NuVasive argued that if a person of ordinary skill were to resize the implants of the primary references according to the dimensions identified in Michelson, the resulting modification would be an implant that is oversized in both length and width, rather than a long and narrow implant as specifically claimed. In particular, if a person of ordinary skill had been motivated to increase the length of the implants disclosed in the primary references in light of Michelson, they would have also increased the width in light of Michelson, leading to an implant that did not meet the length-to-width ratio requirement of the challenged claims. A310-13; A5921-24.

B. Medtronic's New Proposed Revised Grounds of Unpatentability in Reply

In response to NuVasive's argument, Medtronic advanced in its Replies new, revised grounds of unpatentability. In particular, for the first time in its Replies, Medtronic identified Figure 18 of Michelson, showing a single modular member of a different modular implant embodiment and its description in the specification, and argued that the modular member had "a length-to-width ratio of 2.5:1 or more." A350-51; A5973.

FIG. 18



A784. Figure 18 is described as "similar to the spinal fusion implant 900," which is the embodiment Medtronic had relied upon in its Petitions, "but has a narrower width." A790, 10:49-54. To support the specific claimed ratio, Medtronic cited to new testimony from its expert, submitted for the first time with its Replies, that simply stated "one of ordinary skill in the art, ***by comparing the relative sizes of the implants shown in Michelson*** would have readily understood that implant 900 [*sic*] had a width in the range of 12 mm to 16 mm, or approximately half that, or

less, of implant 900, which Michelson describes as having a width 'in the range of 24 mm to 32 mm.'" A2777-78 ¶ 28; A8443-44 ¶ 28. Medtronic did not mention that the described purpose of the modular implant embodiment was so that multiple narrower modular members could be assembled into a single wide modular implant: "The spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae." A790, 10:49-55.

NuVasive requested authorization to file motions to strike Medtronic's new arguments and evidence, or in the alternative, to file surreplies to address the new arguments and evidence. A421; A5992. The Board denied NuVasive's request, prohibiting NuVasive from filing any such motion, stating that "[t]he Board will determine whether [Medtronic's] reply and evidence are outside the scope of a proper reply and evidence when the Board reviews all of the parties' briefs and prepares the final written decision." *Id.*

At Oral Hearing, during NuVasive's response time, the Board again would not allow NuVasive to address Medtronic's new argument, stating "So I think you just need to stick with – ***you can point out what they argue, but you should not be responding to it at this hearing***." A544 (emphasis added). As expected, during its rebuttal time, Medtronic identified Figure 18 and argued that it disclosed an

embodiment that had a length two-and-a-half times greater than its width. A565. NuVasive properly objected, but the Board again refused to grant NuVasive any chance to respond to Medtronic's new arguments and instead assured NuVasive that the Board's decision would ignore any new arguments:

> We understand your argument, your position, as you've articulated this in several prior conference calls. We are aware of our rule, too, that says that the reply needs to be responsive to the Patent Owner response. ***So, I think you just have to let the process take place and we will take it all under advisement when we write our final decision.*** A566 (emphasis added).

C. The Board Devises its Own Distinct New Grounds of Unpatentability Despite Preventing NuVasive from Addressing the Issue

The Board did not, however, simply accept Medtronic's revised grounds for unpatentability—nor did they ignore the revised grounds as untimely as would have been appropriate. Instead, the Board devised yet another revision of the proposed grounds of unpatentability. During Medtronic's rebuttal time at Oral Hearing, it urged the Board that it could simply "look at the pictures" in Michelson and find a disclosure of the claimed implant's dimensions:

> [MR. SCHWARTZ, Counsel for Medtronic:] But there is no dispute, based on NuVasive's response,[3] that Michelson teaches long,

[3] Counsel for Medtronic repeatedly emphasizes that he is "pointing to NuVasive's response" because "[t]hey don't get an opportunity to just say stuff

narrow implants. There is no dispute that Michelson teaches a greater than 40-millimeter implant, and that Michelson teaches an 18-millimeter wide implant.

JUDGE MEDLEY: Is that within one embodiment when you go greater than 40, that 18?

MR. SCHWARTZ: It is not necessarily within one embodiment, Your Honor.

JUDGE MEDLEY: ***So, where is that teaching that you have that once you get greater than 40, that it's in Michelson that it would be two and a half to one?***

MR. SCHWARTZ: I will go back to NuVasive's response, switch back to the previous image. ***That embodiment, each one of those implants, of the three of them, are plainly a 2.5:1 implant. You could see it just from the evidence.***

* * *

JUDGE SIU: ***So, did you get that ratio just by looking at the picture?***

MR. SCHWARTZ: ***Just by looking at the picture.***

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about the art and mischaracterize it." A566. NuVasive did not discuss Figure 18 of Michelson, or its description, in its Patent Owner Responses. *See, e.g.*, A310-13. And the Board did not allow NuVasive to address any of these issues at the Oral Hearing.

JUDGE SIU: ***Is there anything in the text that I can*** –

MR. SCHWARTZ: Well, there's certainly the language that NuVasive pointed you to, from the specification, now it doesn't give specific dimensions, but it does say that there is a narrower embodiment, and it refers to figures 19 and [18] for that narrower embodiment. Figure 19 essentially has three implants of figure [18].

* * *

JUDGE MEDLEY: ***Just by looking at the picture?***

MR. SCHWARTZ: ***Simply by looking at the pictures***, by reading it in the context of the disclosure, by what Dr. Hynes has testified to, and I believe we've referred to in Dr. Hynes' first declaration, right, and this is implant 1000, which is more narrow, has the same length as implant 900 that we talked about being greater than 40, but it's narrower. And, so, the widths that we are talking about that Mr. Amon showed you, you can select narrower ones. And there's absolutely no reason why you would modify the teaching of the primary reference, the 2.5:1 reference, Telamon, Synthes and Frey, all of them at least 2.5:1, and follow the teachings that are consistent with Michelson. There is no inconsistency in making those references longer and still maintaining the appropriate width to keep it at 2.5:1 in the primary reference. It's not inconsistent with the teachings of Michelson. Michelson does not teach away from that combination.

A566-69 (emphases added).

But in finding most of the claims obvious, the Board went beyond even Medtronic's untimely reply argument. Rather than relying on a simple visual inspection of Figure 18 of Michelson as suggested by Medtronic, the Board instead conducted its own additional analysis of the description of that figure. In particular, the Board concluded that it would have been obvious to one of ordinary skill in the art to resize the primary references to have the supposed dimensions of Michelson's Figure 18:[4]

> Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the preferred width being 26 mm." Ex. 1005, 10:40–41, 44–47 [A790, 10:40-41, 44-47]. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. ***In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space."*** Ex. 1005, 10:52–54 [A790, 10:52-54]. ***For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant***

[4] In IPR2013-00508, the Board also purported to "credit the testimony of [Medtronic's expert] that Michelson discloses a spinal implant with a length that is greater than 40 mm and at least 2.5 times the width." A22. The cited testimony was only provided with Medtronic's Reply. A8419. And the cited testimony refers to a printout from the Food and Drug Administration website that apparently "lists approved spinal fusion implants." A8430-31 ¶ 12 (citing A8009-12). It has no apparent bearing on the disclosure of the Michelson reference.

> ***would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm)***.
>
> Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1. A9 (emphasis added); *see also* A22-23 (same).

Had NuVasive been allowed to respond, it would have responded that Michelson's modular implant was consistent with NuVasive's contention that Michelson taught long and wide implants, that no rationale had been articulated to make a long and narrow implant, and that the primary references could not be suitably modified for use as modular members of a modular implant. NuVasive also would have presented evidence regarding the state of the art of modular implants at the time. But again, NuVasive had no opportunity to respond.

The Board concluded that claim 18, which depends from claim 1 and further requires a specific width of 18 mm, was not obvious, because the Board could not identify any embodiment disclosed by Michelson that was both longer than 40 mm and had a width of 18 mm. A9-10; A31.

The Board never addressed any determination it may have made regarding whether obviousness grounds based on the embodiment disclosed in Figure 18 of Michelson were properly presented in Medtronic's Petitions.

SUMMARY OF ARGUMENT

The Board exceeded its authority by relying on new grounds of unpatentability, disregarding appropriate procedure and substituting its own speculation for record evidence, in determining the patentability of the challenged claims. Consequently, its determination that claims 1-5, 10, 11, 14-17, and 19-28 of the '334 patent are obvious should be reversed.

First, the Board erred as a matter of law by crafting and relying on new grounds of unpatentability in its Final Written Decisions while explicitly refusing to give NuVasive a chance to respond. Medtronic did not identify in its Petitions the embodiment of Michelson that the Board ultimately relied on in its Final Written Decisions for the claim requirement at issue. Even after Medtronic belatedly pointed to the embodiment in its Replies, the Board did not even adopt Medtronic's arguments but instead performed its own calculations to arrive at the claimed dimensions. Throughout the IPR proceedings, NuVasive never had any opportunity to respond to the Board's ultimate basis for finding unpatentability. Indeed, the Board expressly dismissed NuVasive's attempts to respond, insisting that NuVasive trust in the process instead. In relying on new grounds for its determination of unpatentability, the Board exceeded its authority, violating its own rules and regulations, the governing statute, and the Administrative Procedure Act. Accordingly, the Board's determination of obviousness should be reversed.

Second, the Board erred in finding that Michelson taught the claimed dimensions. Michelson does not describe the dimensions of the implant shown in Figure 18, and it was error for the Board to fill that void with its own speculation, especially where no record evidence supported finding that the Figure 18 implant had the claimed dimensions. In particular, there is no record evidence to support the Board's calculating the dimensions of one embodiment based on the dimensions of a different embodiment. Because the record fails to support the Board's findings regarding the claimed dimensions, the Board's determination of obviousness should be reversed.

Finally, the Board erred in concluding that it would have been obvious to modify the primary references to have the claimed dimensions. Michelson taught that spinal fusion implants that were both long and wide were preferred, in contrast to the requirement of the claims of, *inter alia*, a long and relatively narrow implant. The disclosure in Michelson of narrower modular members designed to be assembled to create a single wide modular implant is not inconsistent with that teaching. Nothing in Michelson suggests that surgeons should use a long and narrow implant by itself, rather than combined into a wide modular implant. Moreover, the Board's determination of obviousness based on the purported dimensions of the modular member embodiment disclosed by Michelson lacks the basic evidentiary foundation required for any determination of obviousness. There

is no evidence regarding the state of the art of modular implants at the time of the invention of the '334 patent, including whether or not one of skill in the art would have created modular implants. There is no evidence whether or not the implants disclosed in the primary references would have been at all suitable for modification and use as modular members in a modular implant or that there would have been any reasonable expectation of success in doing so. Indeed, there is no evidence at all regarding how the primary references would or could be modified for use as modular members of a modular implant, and if they were so modified, whether they would still meet the requirements of the claims. Accordingly, the Board's determination that one of ordinary skill in the art would have modified the primary references to have the claimed dimensions on that basis cannot stand.

ARGUMENT

I. Standards of Review

As a general matter, this Court reviews the Board's conclusions of law without deference and its findings of fact for substantial evidence. *Microsoft Corp. v. Proxyconn, Inc.*, Nos. 2014-1542, -1543, slip op. at 5 (Fed. Cir. June 16, 2015) (citing *In re Gartside*, 2013 F.3d 1305, 1316 (Fed. Cir. 2000)). The "substantial evidence standard requires the reviewing court to ask whether a reasonable person might find that the evidentiary record supports the agency's conclusion." *On-Line Careline, Inc. v. Am. Online, Inc.*, 229 F.3d 1080, 1085 (Fed. Cir. 2000). The

petitioner in an IPR bears the burden of proving unpatentability. 35 U.S.C. § 316(e).

Whether the Board relied on a new ground of unpatentability in its final written decision in an IPR is a legal issue that should be reviewed *de novo* on appeal. *Cf. In re Stepan Co.*, 660 F.3d 1341, 1343 (Fed. Cir. 2011) (in the reexamination context, whether the Board relied on a new ground of rejection is a legal issue reviewed *de novo*).

Obviousness is a question of law based on underlying findings of fact. *Rambus Inc. v. Rea*, 731 F.3d 1248, 1251-52 (Fed. Cir. 2013) (citing *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000)). The underlying factual inquiries are: "(1) the scope and content of the prior art, (2) the differences between the claims and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) objective evidence of nonobviousness." *Id.* at 1252 (citing *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966)).

II. The Board Erred by Relying On New Grounds of Unpatentability in Its Final Written Decisions

The Board's decision should be reversed because it committed legal error by holding the claims unpatentable based on new grounds that were not argued by Medtronic, even though the Board explicitly refused to let NuVasive address any of these issues.

"Under the Administrative Procedure Act [("APA")], the [Board] must ensure that the parties before it are 'fully and fairly treated at the administrative level.'" *Rambus*, 731 F.3d at 1255 (quoting *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011)); *see also In re Biedermann*, 733 F.3d 329, 336 (Fed. Cir. 2013) (the Board is subject to the Administrative Procedure Act) (citing *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999)). In particular, the Board is required to provide patent owners with prior notice of "the matters of fact and law asserted" before an IPR hearing. 5 U.S.C. § 554(b)(3); *see also Rambus*, 731 F.3d at 1255 (quoting *Stepan*, 660 F.3d at 1345).

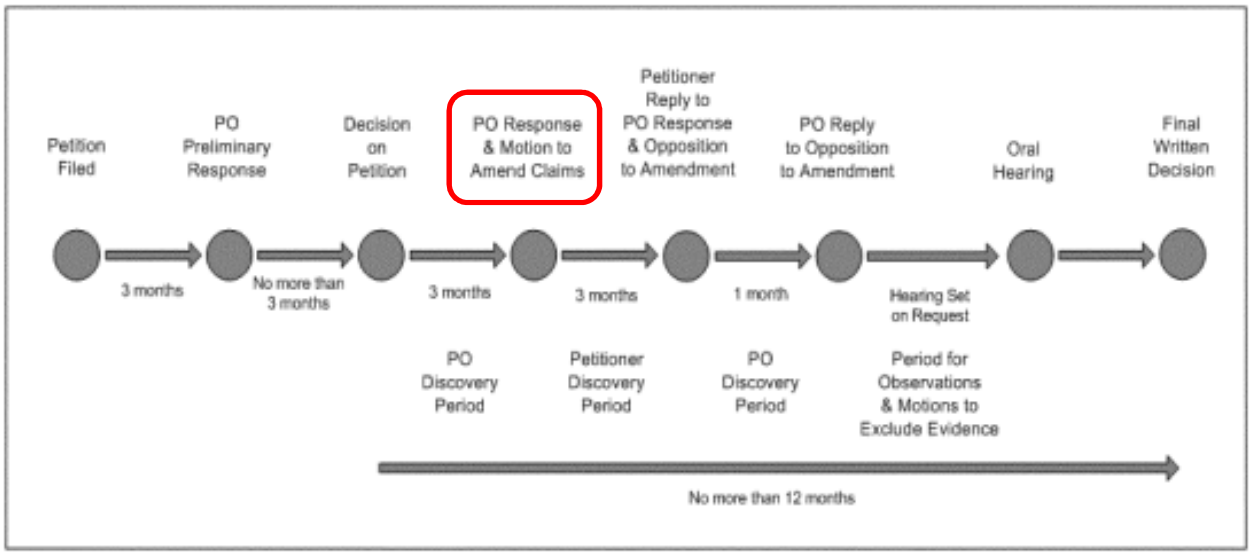
While this Court has not yet decided the issue in the context of an *inter partes* review proceeding, it has long recognized in the examination and reexamination contexts that when a decision of the Board is based on a ground of rejection not previously presented by the examiner, the patent owner has not had a full and fair opportunity to litigate the Board's actual basis of rejection, and the Board's notice obligation has not been fulfilled. *See Stepan*, 660 F.3d at 1343-44 (citing *In re Kumar*, 418 F.3d 1361, 1367-68 (Fed. Cir. 2005) (citing cases)); *see also Progressive Cas. Ins. Co. v. Liberty Mut. Ins. Co.*, Nos. 2014-1466, *et al.*, slip op. at 8-9 (Fed. Cir. Aug. 24, 2015) (nonprecedential) (noting that "the Administrative Procedure Act imposes its own similar obligations on Board action, including in covered business method reviews" and "[t]he APA's requirements

may well embody, in substance, the inquiry at the heart of the new-grounds-of-rejection analysis"). That is, "[t]he Board may not 'rel[y] on new facts and rationales not previously raised to the applicant by the examiner.'" *Rambus*, 731 F.3d at 1255 (quoting *Leithem*, 661 F.3d at 1319). "The ultimate criterion is whether the appellant has had before the PTO a fair opportunity to react to the thrust of the rejection." *Id.* (quotations omitted).

The same concerns apply in the context of IPR, and both the America Invents Act ("AIA") and the Patent Office's regulations set forth procedures that are supposed to ensure that a patent owner has a full and fair opportunity to respond to any unpatentability arguments. For example, the AIA requires that a Petition for IPR "identif[y], in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim[.]" 35 U.S.C. § 312(a)(3). Consistent with the statutory requirements, the Patent Office further prescribed regulations specifying that the petition must include a detailed statement that includes an identification of "how each [] claim is unpatentable under the statutory grounds identified" including "where each element of the claim is found in the prior art patents or printed publications relied upon." 37 C.F.R. § 42.104.

After institution of trial, the statute and regulations provide one opportunity for the patent owner to respond to the instituted grounds, including by submitting

any additional factual evidence and expert opinions on which the patent owner wishes to rely. 35 U.S.C. § 316(a)(8); 37 C.F.R. § 42.120. Under the statute and the Patent Office regulations, the petitioner's case-in-chief must be presented in the petition, and the patent owner's rebuttal case is presented in the patent owner response.



77 Fed. Reg. 48756, 48757 (Aug. 14, 2012) (annotation added). Absent Board authorization to the contrary, the patent owner has no opportunity to respond to grounds of challenge outside the patent owner's response.[5]

Although a petitioner may reply to the patent owner's response (as shown in the annotated figure above), the regulations specify that "[a]ll arguments for the relief requested in a [petition] must be made in the [petition]" and the "reply may

[5] Although the figure shows a patent owner reply to opposition to amendment, that reply would not be an appropriate vehicle to respond to grounds of challenge, and moreover, the provision of such a reply does not apply in IPRs, such as these, where no motion to amend was filed.

only respond to arguments raised in the corresponding [] patent owner response." 37 C.F.R. § 42.23; *see also* 35 U.S.C. § 316(a)(13) ("The Director shall prescribe regulations . . . providing the petitioner with at least [one] opportunity to file written comments within a time period established by the Director."). This, of course, makes sense and is consistent with the APA, as a patent owner has no prescribed means for addressing new theories of alleged unpatentability if they are presented for the first time in the petitioner's reply to the patent owner's response. Indeed, the Patent Office's trial practice guide for proceedings before the Board states that:

> a reply that raises a new issue or belatedly presents evidence will not be considered and may be returned. The Board will not attempt to sort proper from improper portions of the reply. Examples of indications that a new issue has been raised in a reply include new evidence necessary to make out a *prima facie* case for the patentability or unpatentability of an original or proposed substitute claim, and new evidence that could have been presented in a prior filing. 77 Fed. Reg. 48756, 48767 (Aug. 14, 2012).

The Board erred here by failing to enforce these safeguards, and worse yet, by devising its own new rationale while having prohibited NuVasive from ever addressing it. In particular, the Board's decisions relied on an embodiment (Michelson's Figure 18) first identified by Medtronic in its Reply briefs, and further modified based on the Board's own additional calculations. The Board

determined that Michelson disclosed a modular member with a length that was greater than 40 mm and also more than two-and-a-half times the implant's width and that one of ordinary skill would have modified the primary references to have such dimensions:

> Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the preferred width being 26 mm." Ex. 1005, 10:40–41, 44–47 [A790, 10:40-41, 44-47]. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. ***In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space."*** Ex. 1005, 10:52–54 [A790, 10:52-54]. ***For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm)***.
>
> Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1. A9 (emphasis added); *see also* A22-23 (same).

The cited modular member of Michelson, which is shown in Figure 18 of Michelson, was never identified as providing the claimed dimensions in Medtronic's Petitions, so NuVasive did not address it in its Patent Owner Response. And after Medtronic raised Figure 18 for the first time in reply, the Board repeatedly precluded NuVasive from addressing it, assuring NuVasive that the Board would ignore any new arguments. Yet the Board's final decision did the opposite—not only considering the new part of Michelson that it had previously precluded NuVasive from responding to, but also going beyond what even Medtronic had argued.

This Court has previously prohibited the Board from relying on a new portion of a reference to support a new theory of unpatentability without giving the patent owner a chance to respond. *See In re Echerd*, 471 F.2d 632, 635 (C.C.P.A. 1973); *see also Leithem*, 661 F.3d at 1319 (stating that even "reliance on the same statutory basis and the same prior art references, alone, is insufficient to avoid making a new ground of rejection when the Board relies on new facts and rationales not previously raised to the applicant by the examiner"). The same rule should apply for IPR, and it requires reversal here because the Board relied on an embodiment of Michelson that was not cited in the Petitions to supply a claim

requirement (length-to-width ratio) that Michelson was not cited for. NuVasive never had a fair opportunity to react to the thrust of this argument.[6]

Medtronic may argue, as it did before the Board, that it was merely responding to NuVasive's arguments. It cannot be, however, that if a patent owner specifically identifies a hole in a petitioner's *prima facie* case, the petitioner then can fill in the hole with new disclosure, and the patent owner has no opportunity to respond. That a new ground was raised in response to a patent owner's arguments does not negate that it is a new ground. *See Biedermann*, 733 F.3d at 338 (citing *Stepan*, 660 F.3d at 1345; *Leithem*, 661 F.3d at 1317, 1320). NuVasive never had an opportunity to respond to the new grounds, as would have been required in order to satisfy NuVasive's due process rights under the APA.

Moreover, the Board's decision to perform its own calculations to determine the width of the implant shown in Figure 18 of Michelson, rather than relying on a visual inspection of the figure as suggested by Medtronic, is an additional and independent basis for concluding that the Board's unpatentability determinations

[6] *In re Cuozzo Speed Techs. LLC*, No. 2014-1301 (Fed. Cir. July 8, 2015), is not to the contrary because it involved a situation where the alleged "new ground" of unpatentability was identified in the Board's Institution Decision, giving the patent owner ample opportunity to respond, and ensuring that any defect was "washed clean." Slip op. at 8-9. Here, in contrast, the new grounds were not even hinted at until Medtronic's Replies, so NuVasive never had an opportunity to respond to the new grounds, and in fact, the Board expressly prohibited NuVasive from responding.

constituted new grounds of unpatentability. This Court has previously held that "[w]hen a rejection for obviousness is based on overlapping values in the prior art, identification of the values deemed to overlap is material to the rejection." *Kumar*, 418 F.3d at 1367 (holding that the Board providing its own calculations to show claimed values were met constituted a new grounds of rejection). Accordingly, when the Board calculates values itself for the first time, equity dictates an opportunity to respond, and the decision based thereon is a new ground of unpatentability. *See id.* at 1368.

Because the Board's determinations of unpatentability are based on new grounds to which NuVasive had no opportunity to respond, contrary to Patent Office regulations, the AIA, and the APA, the Board's determination of unpatentability should be reversed. NuVasive addresses several consequential errors that the Board made, because NuVasive was not allowed to respond, in Section IV below.

III. The Board Erred in Finding That the Prior Art Taught the Claimed Dimensions by Substituting Its Own Speculation for Record Evidence

The Board's determinations of unpatentability based on obviousness should also be reversed because there is no substantial evidence supporting the Board's conclusion that Michelson discloses an implant with a length greater than 40 mm and at least two-and-a-half times its width. 35 U.S.C. § 103(a) (pre-AIA) provides that a "patent may not be obtained . . . if the differences between the subject matter

sought to be patented and the prior art are such that ***the subject matter as a whole*** would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." (emphasis added). In reviewing the prior art and the claimed subject matter as a whole, nothing in the record provides the assumptions and calculations performed by the Board for the first time in its Final Written Decisions.

In particular, in making its determinations, the Board performed its own calculations based on an assumption that the width of one embodiment of Michelson would simply be half the width of another embodiment:

> Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the preferred width being 26 mm." Ex. 1005, 10:40–41, 44–47 [A790, 10:40-41, 44-47]. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. ***In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space."*** Ex. 1005, 10:52–54 [A790, 10:52-54]. ***For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm)***.

> Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1. A9 (emphasis added); *see also* A22-23 (same).

In other words, the Board avoided Medtronic's suggestion to "simply look[] at the picture." *See* A566-69. If it had, of course, that would itself have been error. *See Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."). Faced with an untimely new theory of unpatentability, based on an erroneous premise that precise dimensions can be derived by "simply looking at the picture," the Board's analysis should have concluded with a finding that Medtronic failed to meet its burden of demonstrating unpatentability in the Petitions. Rather than doing so, the Board compounded the error by looking at the picture and then performing its own additional calculations. In doing so, the Board impermissibly relied on its own speculation rather than record evidence.

This Court has said, in the interference context, that "in a contested proceeding involving resolution of conflicting private claims to a valuable privilege, it is particularly important that the agency's decision on issues of fact be limited to the written record made before the agency." *Brand v. Miller*, 487 F.3d

862, 868-69 (Fed. Cir. 2007) (quotation omitted). The detailed regulations governing IPR, borrowed from interference proceedings, "highlight the Board's role in such cases as an impartial adjudicator of an adversarial dispute between the two parties." *See id.* Accordingly, "in the context of a contested case, it is impermissible for the Board to base its factual findings on its expertise, rather than on evidence in the record[.]" *Id.*

Perhaps unsurprisingly given that it is the basis of a new ground first introduced in the Board's Final Written Decisions, as discussed above, the Board's analysis regarding the modular member disclosed by Michelson is based entirely on the Board's own speculation, rather than record evidence. The Board's conclusion that "[t]hus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width" is not supported by any citation to the record. The Board did not anchor in the record its conclusion that one of ordinary skill in the art would have deduced from Figure 18 of Michelson and the description of it as "narrower" that the disclosed modular member has a length greater than 40 mm and more than two-and-a-half times its width. Lacking an explanation in the record as to how to determine the dimensions of the modular member, the Board substituted its own speculation for record evidence that Medtronic was obligated to provide in its Petitions. *See Brand*, 487 F.3d at 870. The Board's finding that one

of ordinary skill would recognize Figure 18 of Michelson as having the required dimensions requires detailed inferences as to the nature of the described modular implants, which "demonstrates the inappropriateness of its approach." *See Brand*, 487 F.3d at 870-71. Under such circumstances, the Board's decision is not supported by substantial evidence in the record. *Id.*

Because the Board substituted its own speculation for record evidence, substantial evidence does not support the finding that Michelson discloses an implant with a length greater than 40 mm and at least two-and-a-half times its width as required by the challenged claims, and the Board's determinations of obviousness should be reversed.

IV. The Board Erred in Concluding It Would Have Been Obvious to Modify the Primary References to Use the Claimed Dimensions

The Board further erred in concluding that it would have been obvious to use the claimed dimensions based solely on a single inapposite embodiment. "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference . . . would be led in a direction divergent from the path that was taken by the applicant[.]" *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir.

1994)) (alterations omitted). And if the combination of two references "'would produce a seemingly inoperative device,' then they teach away from their combination." *Id.* (quoting *In re Sponnoble*, 405 F.2d 578, 587 (C.C.P.A. 1969). Similarly, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no rationale to make the proposed modification. *Id.* (citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984)). And a proper determination of obviousness requires a reasonable expectation of success. *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1344 (Fed. Cir. 2013) (citing *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1375 (Fed. Cir. 2013); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991)). Because Michelson teaches wide implants, and there is no evidence to support the conclusion that one of skill in the art could or would modify the primary references somehow for use as "narrower" modular members in a modular implant as disclosed by Michelson, the Board's determination of obviousness should be reversed.

Rather than suggesting an implant with a length more than two-and-a-half times its width, Michelson consistently suggests that implants should be made both long and wide:

> An ***oversized*** spinal implant for translateral insertion into the disc space between two vertebrae [*sic*, with] ***a length that is greater than one half of the transverse width of the vertebrae and is greater***

> ***than the depth of the vertebrae***. The translateral implant of the present invention has a height that is greater than the height of the disc space between two adjacent vertebrae so as to engage both of the vertebrae. The ***width of the implant need be only slightly less than the depth of the vertebrae themselves***. The translateral spinal fusion implant of the present invention has ***more surface area*** of contact and thus permits ***greater stability*** so as to withstand torque, and in the case of a threaded implant, increases the depth which any threads are able to penetrate the vertebrae. A777 (emphases added).

The Detailed Description of Michelson further describes and touts the importance of implants being both long and ***wide***, claiming for example: "[a]s a result of the large length and ***diameter*** of the implant 100a, a large surface area of contact between the implant 100a and the vertebrae V1 is possible creating a highly stable construct." A788, 6:51-54. Michelson explains that the proposed implants have "a much greater surface area of contact with the vertebra V1 than was previously possible." A788, 6:54-56.

Accordingly, NuVasive argued that one of ordinary skill in the art modifying the primary references to have a length greater than 40 mm in view of Michelson, also would have accordingly increased their width in view of Michelson. A310-13; A5921-24. The Board's response, as discussed above, was simply that Michelson disclosed a "narrower" modular member and "[t]hus, it would have been obvious." A9; *see also* A23. Again as discussed above, because the argument related to the

modular member embodiment of Michelson was not contained in Medtronic's Petitions, it is unsupported by record evidence. And so the Board's conclusion falls far short of an "articulated reasoning with some rational underpinning." *See KSR*, 550 U.S. at 418 (quoting *Kahn*, 441 F.3d at 988). It completely fails to "explain what reason or motivation one of ordinary skill in the art at the time of the invention would have had" to make such a modification. *InTouch Techs., Inc. v. VGo Comm'ns, Inc.*, 751 F.3d 1327, 1348-49 (Fed. Cir. 2014).

Indeed, the "narrower" modular member is in fact consistent with Michelson teaching wider implants. Contrary to Medtronic's belated basis of challenge, the identified embodiment of Michelson does not teach a single "narrow" implant. Instead, Michelson discloses an alternate embodiment that describes a narrower modular member designed for combination with other modular members so as to form a single modular implant that is oversized in both length and width—just as with the other Michelson implants:

> The spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width ***such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion*** within the disc space D between the adjacent vertebrae. A790, 10:50-55.

Medtronic's only apparent response is that the cited language is permissive, because it uses the word "may." A566. To the contrary, it is clear that "may" is

being used to express purpose, not permission. In any case, Michelson does not provide any "articulated reasoning with some rational underpinning" for one of ordinary skill in the art to make a modular member that is both long and narrow other than for use as a component to be assembled into a single oversized modular implant.

Thus, the conclusion that one of skill in the art would have modified the primary references to have the claimed dimensions in light of the "narrower" modular member embodiment of Michelson is unsupported by any evidence. For one thing, there is no evidence regarding the state of the art with respect to modular implants at the time of the invention of the '334 patent, including for example, whether or not one would even have pursued a modular implant at that time. Had NuVasive been accorded an opportunity to respond, it would have submitted evidence regarding the state of the art at the time, including that modular implants remain, to this day, uncommon. And what modular implants do now exist are specifically designed to incorporate complicated systems of rails and slots and locking systems, which, at face value, would appear impractical modifications to the cited prior art implants.

And even assuming one of ordinary skill in the art at the time of the invention of the '334 patent would have been interested in attempting design of a modular-type implant, there is still not any evidence that the primary references

modified to have the claimed dimensions would have been at all suitable for combination "in a modular fashion for insertion." For example, it is readily apparent from both (1) the shape of the implant disclosed by Frey, and (2) the posteriolateral procedure by which the Frey implant was designed to be inserted, which involves inserting and then turning the implant within the disc space, that modifications beyond resizing would be required in order to make any implant disclosed by Frey suitable to be "combined in a modular fashion for insertion." Unlike the blocky modular members of Michelson, it is difficult to believe that one would, or even could, insert multiple boomerang-shaped implants of the type described in Frey side-by-side, presumably nestled in the disc space like complementary spoons.

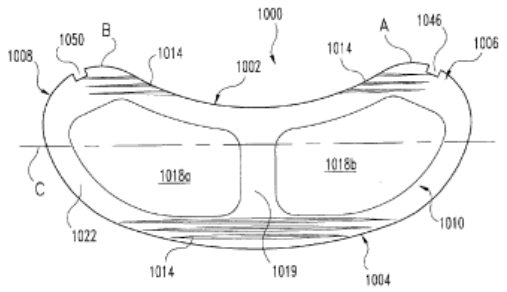
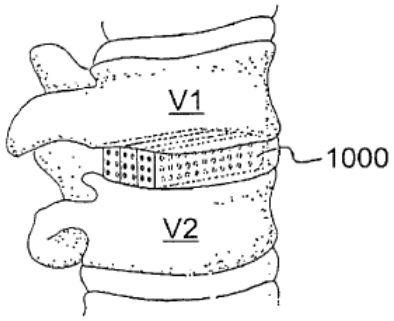


Fig. 55

A740 (Frey)

FIG. 19



A784 (Michelson)

Finally, there is no evidence that the primary references, if modified in some unspecified manner in order to make them suitable for use as modular members in a modular implant, would still disclose the specific size and dimension requirements of the claims. For example, the Board suggests that the width of the

implant disclosed by Frey would be modified to have the purported width of the modular member shown in Figure 18 of Michelson. But it's unclear whether the proposed new width of Frey is with respect to Frey's overall width or the width at its center (as illustrated in the annotated figure below), and thus whether the proposed modification would actually meet the challenged claims' maximum lateral width requirements.

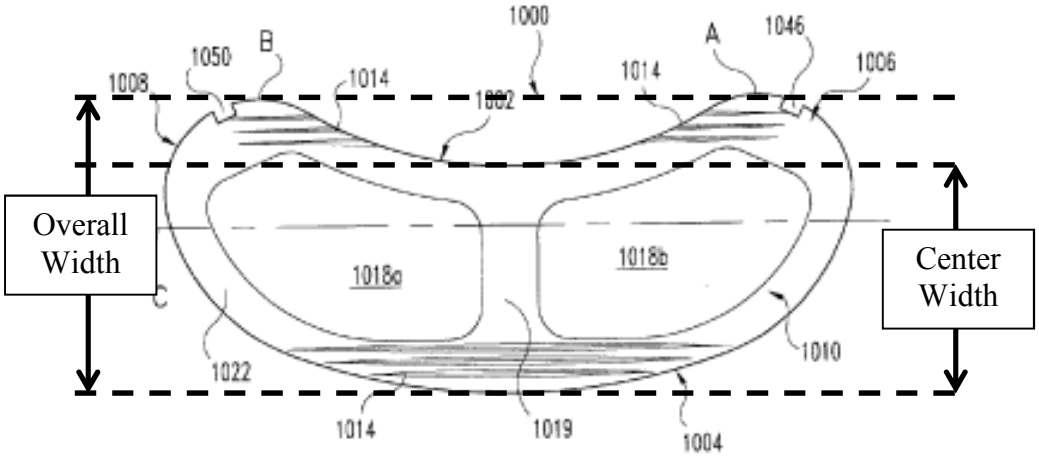


Fig. 55

As the above discussion illustrates, the Board's crafting new grounds of unpatentability in its Final Written Decisions and substituting its own speculation for record evidence raises more questions than answers. These apparent yet unresolved issues provide independent reasons why the Board's determinations of unpatentability should be reversed.

CONCLUSION

The Board's ruling that claims 1-5, 10, 11, 14-17, and 19-28 are unpatentable as obvious should be reversed.

Date: August 26, 2015

Respectfully submitted,

/s/ Michael T. Rosato
Michael T. Rosato
Counsel for Appellant NuVasive, Inc.

CERTIFICATE OF SERVICE

I certify that counsel for the parties have been served with a true and correct copy of the foregoing document via the Court's CM/ECF system on August 26, 2015.

/s/ Michael T. Rosato
Michael T. Rosato
Counsel for Appellant NuVasive, Inc.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2). The brief contains 10,324 words, excluding the parts of the brief exempted by Fed. R. App. P. 32 (a)(7)(B)(iii) and Fed. Cir. R. 32(b). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman.

Date: August 26, 2015

Respectfully submitted,

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ADDENDUM

INDEX

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571-272-7822

Paper 43
Date: February 11, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2013-00507
Patent 8,187,334 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

Medtronic, Inc. ("Petitioner") filed a Petition (Paper 1) ("Pet.") seeking *inter partes* review of claims 1–5, 10, 11, and 14–28 of U.S. Patent No. 8,187,334 B2 (Ex. 1013, "the '334 patent") pursuant to 35 U.S.C. §§ 311–319. On February 13, 2014, the Board instituted an *inter partes* review of claims 1–5, 10, 11, and 14–28 (Paper 7) ("Dec. on Inst.").

Subsequent to institution, Nuvasive, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 17) ("PO Resp."), and Petitioner filed a Reply (Paper 24) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence. Paper 34. Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 37) ("Opp."), and Patent Owner filed a Reply (Paper 41) ("PO Reply"). An Oral Hearing was conducted on November 18, 2014, pursuant to Requests for Oral Argument filed by Petitioner (Paper 28) and Patent Owner (Paper 29). Patent Owner also filed a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Richard A. Hynes, M.D. (Paper 35, "Hynes Obs.") and a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Loic Josse (Paper 34, "Josse Obs."). Petitioner filed a Response to each of Patent Owner's Motions for Observation (Paper 39, "Hynes Obs. Resp."; Paper 40, "Josse Obs. Resp.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent are unpatentable, but has not shown by a preponderance of the evidence that claim 18 of the '334 patent is unpatentable.

A. The '334 Patent

The '334 patent describes a spinal fusion system, including a spinal fusion implant and an insertion instrument. Ex. 1013, 5:6–9. The spinal fusion implant is introduced into the disc space via a lateral approach to the spine or via a posterior, anterior, antero-lateral, or postero-lateral approach,

and is made from a radiolucent material, such as PEEK (poly-ether-ether-ketone). *Id.* at 5:10–15, 5:29–33. In one embodiment, the spinal fusion implant has a width ranging between 9 and 18 mm and a length ranging between 25 and 44 mm. *Id.* at 5:17–19.

B. Illustrative Claim

Claim 1 is illustrative of the claimed subject matter of the '334 patent, and is reproduced as follows:

> 1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:
>
> an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;
>
> wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;
>
> wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and halftimes greater than said maximum lateral width;
>
> at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein

the longitudinal aperture length is greater than the lateral aperture width; and

at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

C. Instituted Challenge

This *inter partes* review involves the following ground of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Frey[1] and Michelson[2]	§103	1–5, 10, 11, 14, 15, and 18–28

D. Claim Interpretation

The parties appear to agree on the interpretation of claim terms of the '334 patent. Having considered whether the construction set forth in the Decision to Institute should be changed in light of evidence introduced during trial, we are not persuaded any modification is necessary. Therefore, we maintain the constructions set forth in the Decision to Institute and determine that no other express constructions are necessary. *See* Dec. on Inst. 4-5.

[1] Frey, US 2002/0165550 A1, filed Nov. 7, 2001 (Ex. 1103).
[2] Michelson, US 5,860,973, issued Jan. 19, 1999 (Ex. 1105).

II. ANALYSIS

A. Frey and Michelson

We conclude that Petitioner has shown by a preponderance of the evidence that all of the limitations of claims 1–5, 10, 11, 14, 15, and 19–28 are taught or suggested by the combination of Frey and Michelson. Pet. 52–56. Claim 1 recites an implant that "has a longitudinal length greater than 40 mm" and that the longitudinal length (that is greater than 40 mm) is "at least two and a half times greater than the maximum lateral width." Claims 2–5, 10, 11, and 14–28 depend from claim 1.

Petitioner argues that "Frey provides that the length of the implant is 'sufficient to span the disc space'" and discloses "using the disclosed implant in lateral . . . approaches to the disc space." Pet. 53, 54 (citing Ex. 1003 ¶ 0130). Petitioner also argues that Michelson discloses "a spinal fusion implant – that is used in a lateral . . . fashion . . . that has a longitudinal length greater than 40 mm." Pet. 56 (citing Michelson 10:41–46). Hence, Petitioner argues that it would have been obvious to one of ordinary skill in the art, given Frey's laterally inserted spinal implant, to have provided that the laterally inserted spinal implant measures greater than 40 mm in length, as disclosed by Michelson.

Patent Owner argues that it would not have been obvious to combine the teachings of Frey and Michelson to achieve an implant with a length greater than 40 mm as disclosed by Michelson because "the proposed modification would render the resulting implant inoperable for Frey's intended purpose." PO Resp. 27 (citing Ex. 2020 ¶¶ 108, 109). Patent Owner further characterizes the "intended purpose" of Frey to be "to provide

the capability for posterolateral TLIF procedure." PO Resp. 30. However, Frey discloses "spinal surgery from a unilateral posterior approach, a lateral approach, an oblique approach, and through laparoscopic or endoscopic instruments from any of a variety of angles or approaches to the spine." Ex. 1003 ¶ 184. Given that Frey discloses spinal surgery performed "from any of a variety of angles or approaches," and not just from the posterolateral approach, we are not persuaded by Patent Owner that the "intended purpose" of Frey is to perform spinal surgery from a posterolateral approach, specifically.

Rather, Frey discloses that "spinal discs may be displaced or damaged" and "may result in nerve damage, pain, numbness, muscle weakness, and even paralysis." Ex. 1003 ¶ 3. According to Frey, these issues are addressed by "surgical correction of a collapsed disc space" by "discectomy . . . often followed by restoration of normal disc space height and bony fusion of the adjacent vertebrae to maintain the disc space height." *Id.* Hence, the "intended purpose" of the implant of Frey, as explicitly disclosed by Frey, is to correct surgically a collapsed disc space, to restore normal disc space height, and to provide bony fusion of the adjacent vertebrae. We disagree with Patent Owner that incorporating Michelson, which discloses an implant that "engage[s] more of the adjacent vertebrae," (Ex. 1105, 3:49–50) would have rendered the resulting implant inoperable for Frey's intended purpose of surgically correcting a collapsed disc space or providing bony fusion of the adjacent vertebrae.

Even if the "intended purpose" of Frey is to practice a "TLIF procedure," as Patent Owner contends, we are not persuaded by Patent Owner's argument that an implant measuring greater than 40 mm in length

would be inoperable in a "TLIF procedure." As Petitioner explains, U.S. Patent No. 7,815,682 (the '682 patent) demonstrates that when performing "Transforaminal lumbar interbody fusion (TLIF) procedures," one of ordinary skill in the art may employ a spinal implant with "a length ranging between 20 and 45 mm." Pet. Resp. 6 (citing, Ex. 1028, 1:37–38; 4:45). The '682 patent does not disclose that the use of a spinal implant measuring up to 45 mm in length would render the "TLIF procedure" inoperable.

Patent Owner argues that "it would still not be obvious to enlarge the boomerang implant of Frey to exceed 40 mm because such boomerang implants are sized and shaped to sit within a portion of the intra-annulus region of the disc space inside the annulus" and that a spinal implant measuring greater than 40 mm in length presumably would extend beyond the "intra-annulus region of the disc space inside the annulus." PO Resp. 32 (citing Ex. 2020 ¶¶ 98, 100, 108). However, even if Patent Owner is correct that the implant of Frey is a "boomerang" implant, Patent Owner provides insufficient evidence that a boomerang implant must fit within the "intra-annulus region of the disc space" or that even if an implant is restricted to the "intra-annulus region of the disc space," that such an implant could not measure greater than 40 mm in length.

Patent Owner's declarant (Dr. Hansen A. Yuan) testifies that, "[i]n my experience, [boomerang] implants, like those described in Frey, are generally positioned within a portion of the intra-annulus region within the disc annulus." Ex. 2020 ¶ 98. Even if positioned and restricted to being completely within the intra-annulus region was a requirement of implants "like those described in Frey," as Dr. Yuan testifies (Ex. 2020 ¶ 98), neither Patent Owner nor Dr. Yuan demonstrates that an implant measuring greater

than 40 mm in length must extend beyond the intra-annulus region (i.e., would not fit within the intra-annulus region). In any event, Dr. Yuan merely testifies that "[i]n my experience, [boomerang] implants, like those described in Frey, are generally positioned within a portion of the intra-annulus region within the disc annulus." Ex. 2020 ¶ 98. Even if implants similar to those disclosed by Frey "generally" are positioned within a certain region, Dr. Yuan does not assert or demonstrate persuasively that such implants are required to be so positioned. We are not persuaded by Patent Owner's argument.

Dr. Yuan further testifies that he "see[s] no description in Frey as to how one of skill in the art would insert the Frey device using a 'lateral approach'." Ex. 2020 ¶ 100. However, as Petitioner explains, Michelson discloses "an implant inserted laterally." Pet. 54. We are not persuaded by Patent Owner's argument.

Patent Owner argues that "[i]f it were obvious . . . to size such boomerang implants to exceed 40 mm . . . Medtronic would offer such implants. It does not." PO Resp. 35. We are not persuaded by Patent Owner's argument because "the test [for obviousness] is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). As such, we do not see the relevance of whether Medtronic offers a particular type of implant for sale or not.

Patent Owner also argues that the combination of Frey and Michelson fails to disclose or suggest "longitudinal length is at least two and half times greater than said maximum lateral width" and that "if one were to modify Frey according to the dimensions of Michelson, the resulting implant would

have a length between 32-50 mm ***and*** a width between 24-32 mm." PO Resp. 38, 39 (citing Ex. 1013, claim 1; Ex. 1005, 10:41–46). Patent Owner further argues that "Michelson discloses no implant that is both long (over 40 mm) and narrow (length at least 2.5 times width)." PO Resp. 41. However, Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the preferred width being 26 mm." Ex. 1005, 10:40–41, 44–47. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space." Ex. 1005, 10:52–54. For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm).

Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1.

Claim 18 depends from claim 1 and further recites that the maximum lateral width of the implant is approximately 18 mm. Petitioner argues that Michelson discloses an implant that "would have a . . . maximum lateral width in the range of 14 to 26 mm." Pet. 57 (citing Ex. 1005, 7:26–30). Patent Owner, however, points out that, "Michelson discloses no implant that is longer than 40 mm *and* has a width of 18mm." PO Resp. 42 (citing

Ex. 2020 ¶¶ 94, 110–112). Instead, even if the cited implant of Michelson has a maximum width of 18 mm, as argued by Petitioner, Michelson discloses that the implant measures 12-30 mm in length, which is less than 40 mm, in contrast to the requirement of claim 18 of an implant length that is greater than 40 mm. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified Michelson's implant to have a length greater than 40 mm and a maximum width of 18 mm.

Petitioner also asserts Michelson incorporates by reference U.S. Patent No. 5,772,661 (Ex. 1046, "Michelson '661") and U.S. Patent No. 5,484,437 (Ex. 1048, "Michelson '437") and argues that "Michelson '661"discloses an implant with a maximum width of 18 mm. *See* Pet. 57–58. Michelson '661 discloses an implant with a width "in the range of 10 mm to 30 mm." Ex. 1046, 10:31. Even if Michelson '661 discloses an implant with a maximum width of 18 mm (as within the range of 10 mm to 30 mm), Michelson '661 discloses that the length of the implant is "less than the known transverse width W (side to side) of the vertebrae T7 and T8." Ex. 1046, 10:21–23. Petitioner does not assert, or demonstrate sufficiently, that the "known transverse width W (side to side) of the vertebrae T7 and T8" (corresponding to the length of the implant) is greater than 40 mm, as required by claim 18. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

Petitioner also cites U.S. Patent No. 5,484,437 (Ex. 1048, "Michelson '437") as disclosing an implant with a maximum width of 18 mm. *See* Pet. 57–58. Even if Michelson '437 discloses an implant with a maximum width of 18 mm, Petitioner does not assert, or demonstrate sufficiently, that Michelson '437 also discloses that the implant with a maximum width of 18 mm measures greater than 40 mm in length, as required by claim 18. Nor does Petitioner articulate reasoning, with some rational underpinning, to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

B. Secondary Considerations

Patent Owner argues "the evidence of commercial success here and its nexus to the claimed invention is sufficient to overcome [the proposed ground of unpatentability]" and that "the detailed testimony establishes a nexus between NuVasive's CoRoent XL implants and the invention of the ''334 patent . . . proves the commercial success of the product." PO Resp. 44.

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Even assuming that NuVasive's CoRoent XL implant experienced "commercial success," as Patent Owner asserts, Patent Owner has not demonstrated sufficiently that there is a nexus between the merits of the *claimed* invention and the evidence offered. For example, Patent Owner argues that NuVasive "pioneered the market for lateral, trans-psoas interbody fusion surgeries," (PO Resp. 44) but fails to demonstrate sufficiently that any of the disputed claims recite "lateral, trans-psoas interbody fusion surgeries." We are not persuaded by Patent Owner's arguments.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the Declaration of Loic Josse (Ex. 1116, "Josse Declaration"). We did not rely on the Josse Declaration in this decision. Therefore, Patent Owner's motion to exclude is *dismissed* as *moot*.

D. Motion for Observation

Patent Owner's observations are directed to the cross-examination testimony of Richard A. Hynes, M.D. (Ex. 35), who was cross-examined after Petitioner filed its Reply. We have considered Patent Owner's observations and Petitioner's responses in rendering our decision, and have accorded the testimony the appropriate weight as explained above. *See* Obs. 1–10.

Patent Owner also submits observations to the cross-examination testimony of Loic Josse (Ex. 34). As previously discussed, we did not rely

on the Josse Declaration in this decision. Therefore, we have not considered Patent Owner's observations directed to the cross-examination testimony of Loic Josse.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–5, 10, 11, 14–17, and 19–28 are unpatentable over Frey and Michelson under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claim 18 is unpatentable over Frey and Michelson under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2013-00507
Patent 8,187,334 B2

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Paper 50
Date: June 9, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2013-00507
Patent 8,187,334 B2

Before PATRICK E. BAKER, *Trial Paralegal*.

ERRATA

The February 11, 2015, Final Written Decision (hereinafter "Decision") is revised as follows to correct the following error:

On pages 2 and 13 of the Decision, the claims subject to the Decision was listed as "claims 1–5, 10, 11, 14–17, and 19–28"; however, the Board declined to institute trial as to claims 16 and 17. Paper 7.

Therefore, the subject claims as listed on pages 2 and 13 of the Decision is withdrawn and replaced with the following new listing:

claims 1–5, 10, 11, 14, 15, and 19–28

All other portions of the Decision remain unchanged. Any confusion

caused by the above-noted error is regrettable.

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Paper 48
Date: February 11, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner,

v.

NUVASIVE, INC.,
Patent Owner.

Case IPR2013-00508
Patent 8,187,334 B2

Before SALLY C. MEDLEY, LORA M. GREEN, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

Medtronic, Inc. ("Petitioner") filed a Petition (Paper 1) ("Pet.") seeking *inter partes* review of claims 1–5, 10, 11, and 14–28 of U.S. Patent No. 8,187,334 B2 (Ex. 1115, "the '334 patent") pursuant to 35 U.S.C. §§ 311–319. On February 13, 2014, the Board instituted an *inter partes* review of claims 1–5, 10, 11, and 14–28 (Paper 7) ("Dec. on Inst.").

Subsequent to institution, Nuvasive, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 21) ("PO Resp."), and Petitioner filed a Reply (Paper 28) ("Pet. Reply"). Patent Owner also filed a Motion to Exclude Evidence (Paper 34). Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 41) ("Opp."), and Patent Owner filed a Reply (Paper 46) ("PO Reply"). An Oral Hearing was conducted on November 18, 2014, pursuant to Requests for Oral Argument filed by Petitioner (Paper 32) and Patent Owner (Paper 33). Patent Owner also filed a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Richard A. Hynes, M.D. (Paper 38, "Hynes Obs.") and a Motion for Observation on certain cross-examination testimony of Petitioner's declarant, Loic Josse (Paper 39, "Josse Obs."). Petitioner filed a Response to each of Patent Owner's Motions for Observation (Paper 44, "Hynes Obs. Resp."; Paper 45, "Josse Obs. Resp.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent are unpatentable, but has not shown by a preponderance of the evidence that claim 18 of the '334 patent is unpatentable.

A. The '334 Patent

The '334 patent describes a spinal fusion system, including a spinal fusion implant and an insertion instrument. Ex. 1115, 5:6–9. The spinal fusion implant is introduced into the disc space via a lateral approach to the spine or via a posterior, anterior, antero-lateral, or postero-lateral approach,

and is made from a radiolucent material, such as PEEK (poly-ether-ether-ketone). *Id.*at 5:10–15, 5:29–33. In one embodiment, the spinal fusion implant has a width ranging between 9 and 18 mm and a length ranging between 25 and 44 mm. *Id.*at 5:17–19.

B. Illustrative Claim

Claim 1 is illustrative of the claimed subject matter of the ’334 patent, and is reproduced as follows:

> 1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:
>
> an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;
>
> wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;
>
> wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and halftimes greater than said maximum lateral width;
>
> at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and

> a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and
>
> at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

C. Instituted Challenge

This *inter partes* review involves the following grounds of unpatentability:

Reference(s)	**Basis**	**Claims challenged**
Baccelli,[1] Michelson,[2] and SVS[3]	§103	1–5, 10, 11, and 14–28
Baccelli, Michelson, and Telamon[4]	§103	1–5, 10, 11, and 14–28

D. Claim Interpretation

The parties appear to agree on the interpretation of claim terms of the '334 patent. Having considered whether the construction set forth in the Decision to Institute should be changed in light of evidence introduced during trial, we are not persuaded any modification is necessary. Therefore,

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[1] Baccelli, US 2003/0028249 A1, filed Feb. 6, 2003 (Ex. 1104).
[2] Michelson, US 5,860,973, issued Jan. 19, 1999 (Ex. 1105).
[3] Synthes Vertebral Spacer – PR Brochure, Synthes Spine 2002 ("SVS", Ex. 1106).
[4] Medtronic Sofamor Danek, Telamon, Verte-Stack PEEK Vertebral Body Spacer, ©2003 Medtronic Sofamor Danek USA, Inc (Ex. 1107); and Telamon, Posterior Impacted Devices, ©2003 Medtronic Sofamor Danek USA, Inc. (Ex. 1108) (collectively, "Telamon").

we maintain the constructions set forth in the Decision to Institute and determine that no other express constructions are necessary. *See* Dec. on Inst. 5-6.

II. ANALYSIS

A. Baccelli, Michelson, and One of SVS or Telamon (Claims 1–5, 10, 11, and 14–28)

We conclude that Petitioner has shown by a preponderance of the evidence that all of the limitations of claims 1–5, 10, 11, 14–17, and 19–28 are taught or suggested by the combination of Bacelli, Michelson, and one of SVS or Telamon. Pet. 14–60. Claim 1 recites an implant that "has a longitudinal length greater than 40 mm" and that the longitudinal length (that is greater than 40 mm) is "at least two and a half times greater than the maximum lateral width." Claims 2–5, 10, 11, and 14–28 depend from claim 1.

Petitioner argues that "the SVS-PR [implant] has a longitudinal length at least two and half times greater than the maximum lateral width," that "the Telamon [implant] has a 10 mm width, and may have a length of 26 mm [which provides an implant with a longitudinal length at least two and a half times greater than the maximum lateral width]," and that "a skilled artisan . . . inclined to provide an implant for lateral insertion . . . would have been taught by Michelson to make the length of the implant 40 mm or greater" at least in order "to provide more stable support for the vertebra" and because doing so "represents nothing more than an application-specific

dimensional optimization in accordance with the prior art." Pet. 18, 20, 21, 42–44 (citing Ex. 1101 ¶72).

Patent Owner argues that Michelson fails to disclose or suggest an implant with a longitudinal length at least two and a half times greater than the maximum lateral width, "discloses no reason to size an implant to be greater than 40 mm and also narrow," "never suggests that a narrow, 40mm implant would be beneficial or even acceptable," and "did not recognize the benefits of the claimed dimensions." PO Resp. 42–43 (citing Ex. 2020, 24, 117–120). In addition, according to Patent Owner, Michelson discloses "oversized" implants and "discloses no implant that is both long (over 40 mm) and narrow (length at least 2.5 times width)." PO Resp. 43–44 (citing Ex. 1101 ¶ 150; Ex. 2020 ¶¶ 94, 117–119). In addition, Patent Owner's Declarant, Dr. Barton Yuan, testifies that "the '334 patent presents novel dimensions and length-to-width proportions for implants that are greater than 40mm in length that had not been contemplated before . . . ." Ex. 2020 ¶ 47.

However, we credit the testimony of Petitioner's Declarant (Dr. Richard A. Hynes) that Michelson discloses a spinal implant with a length that is greater than 40mm and at least 2.5 times the width. For example, Dr. Hynes testifies that Michelson discloses spinal implants that measure greater than 40mm in length (e.g., 44mm) that is at least 2.5 times the width of the implant (e.g., the width measuring 17mm, which is less than 44mm/2.5 = 17.6mm). Ex. 1157 ¶ 12 (citing Ex. 1118).

In addition, Michelson expressly discloses an implant "with 42 mm being the preferred length" and a width that "approximates the depth of the vertebrae," that measures "in the range of 24 mm to 32 mm," with "the

preferred width being 26 mm." Ex. 1105, 10:40–41, 10:44–47. In other words, Michelson discloses that an implant with a preferred width of 26 mm (or between 24 mm and 32 mm) would approximate the depth of the vertebrae. In one embodiment of Michelson, one implant "has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space." *Id.* at 10:52–54. For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure 26 mm/2 implants = 13 mm, which, when multiplied by a factor of 2.5, would be less than the length of the implant (e.g., preferably 42 mm).

Thus, it would have been obvious to one of ordinary skill in the art to have provided an implant with a length of greater than 40 mm (e.g., 42 mm) and at least 2.5 times the width, as recited in claim 1.

Patent Owner argues that "[i]f the size of the SVS-PR PLIF implant were increased according to the dimensions disclosed by Michelson, the . . . width would be increased from 8 mm . . . to between 24 to 32 mm" and that "if the size of the Telamon PLIF implant were increased according to these dimensions disclosed by Michelson, the . . . width would be increased from 10 mm . . . to between 24 to 32 mm." PO Resp. 31. However, Patent Owner does not explain sufficiently why one of ordinary skill in the art would have increased the width of either the SVS or Telamon implant to 24–32 mm based on Michelson. On the contrary, as argued by Petitioner[5] and

[5] Petitioner argues that "as best exemplified in Figure 18, Michelson discloses long and narrow implants used for lumbar fusion. *See* Ex. 1157 ¶ 28. One of ordinary skill in the art would have understood that the implant 1000 disclosed a width in the range of 12 mm to 16 mm, or smaller, than implant 900, which is described as having a width "in the range of 24 mm to

as previously discussed, Michelson discloses an implant with a length greater than 40 mm and a width such that the total combined width of at least two of such implants would approximate the depth of the vertebrae of approximately 26 mm. Hence, Michelson discloses at least one example in which the width of an implant would be 13 mm with a length of 42 mm. Michelson further discloses that the implant(s) should "be small enough so as to fit into the same limited spinal width." Ex. 1105, 2:51–52. If the width of an implant was increased to 24–32 mm, as suggested by Patent Owner, then the total combined width of the combination of more than one implant as disclosed in Michelson would be 48–64 mm, which would exceed the approximate size of the intervertebral space of 26 mm, also as disclosed by Michelson. As Patent Owner points out, one of ordinary skill in the art would not have considered expanding the size of spinal implants beyond the confines of the intervertebral space because doing so may "compromise[e] the spinal cord, or nerve roots residing in the canal, potentially resulting in paralysis." PO Resp. 37.

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of either SVS or Telamon with Michelson because the implants of SVS or Telamon are both implants "designed with the intended purpose of use in PLIF procedures" but the implants of Michelson are "laterally inserted implants [as opposed to PLIF implants]" such that combining the teachings of either SVS or Telamon with that of Michelson (which, according to Patent Owner,

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32 mm." *See* Ex. 1105, 10:41–44; Ex. 1157 ¶ 28; *see also* Ex. 1148, 14:9–14 (disclosing tube, larger than implant, used to create space for implant "with 20 mm being the preferred outer diameter [of the tube]. . . ."); *id*. at 10:30–34."

discloses lateral implantation with an implant greater than 40 mm in length) "would fully eliminate SVS-PR's and Telamon's specifically intended insertion path and usage, rendering it inoperable for its intended purpose as a PLIF implant." PO Resp. 32–33, 35–37 (citing Ex. 2020 ¶¶ 82–83, 85, 87–88, 113–114).

SVS discloses that "[t]he Vertebral Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture)." Ex. 1106, 1. Hence, the "intended purpose" of the implant of SVS is to replace components within vertebrae. Telamon discloses a process of inserting an implant into an intervertebral space to achieve "decompression of the neural elements" and "satisfactory immobilization of the grafted interspace." Ex. 1108, 9. Hence, the "intended purpose" of the implant of Telamon is to achieve immobilization of the grafted interspace (and/or decompression of neural elements). We disagree with Patent Owner that Michelson, which discloses an implant that "engage[s] more of the adjacent vertebrae," (Ex. 1105, 3:49–50) would have "fully eliminated" the purpose of the SVS or Telamon implants of replacing collapsed, damaged, or unstable intervertebral components or immobilizing the interspace. Instead, the intended purpose of Michelson (a spinal fusion implant) appears to be the same as the intended purpose of either of SVS or Telamon, i.e., to achieve immobilization of the grafted interspace, for example. We are not persuaded by Patent Owner's argument.

Patent Owner argues that "using a 41 mm implant in a PLIF procedure would be extremely dangerous to the patient, risking paralysis or death" due to "the location of blood vessels and the spinal cord" and that "no

responsible surgeon would insert a 41 mm implant [of Michelson] in the PLIF approach intended by Telamon . . . and SVS." PO Resp. 38, 40 (citing Ex. 2020, 114–116). Hence, Patent Owner contends that "Michelson . . . specifically teaches away from inserting a posterior implant large enough to extend out of the disc space." PO Resp. 38–39 (citing Ex. 1105, 2:7–12). As previously described, the Petitioner argues that SVS and Telamon both disclose spinal implants and that "a skilled artisan . . . inclined to provide an implant for lateral insertion . . . would have been taught by Michelson to make the length of the implant 40 mm or greater" at least in order "to provide more stable support for the vertebra" and because doing so "represents nothing more than an application-specific dimensional optimization in accordance with the prior art." Pet. 18, 20, 21, 42–44 (citing Ex. 1101 ¶ 72). Hence, even assuming to be true Patent Owner's contention that "no responsible surgeon would insert a 41 mm implant in the PLIF approach," we are not persuaded by Patent Owner's argument because one of ordinary skill in the art, based on Michelson, would have inserted the "41 mm implant" laterally and not posteriorly. PO Resp. 38, 40 (citing Ex. 2020, 114–116).

In any event, Petitioner submits evidence supporting the contention that the insertion of implants measuring over 40 mm in length via a posterior approach is practiced safely in the art and, therefore, we are not persuaded by Patent Owner that "no responsible surgeon would insert" an implant measuring greater than 40 mm in length posteriorly. For example, Petitioner explains that Tohmeh (US Patent No. 8,623,088 B1 – Ex. 1131) discloses a spinal implant measuring up to 45 mm in length and "approaches a patient's spine posteriorly." Pet. Reply 5 (citing Ex. 1131, 5:32–35); Ex. 1131, 4:3.

Tohmeh does not disclose that such a practice would be "extremely dangerous to the patient, risking paralysis or death." In addition, as Petitioner explains, Patent Owner's Declarant (Dr. Yuan) testifies that a spinal implant measuring greater than 40 mm in length would fit within the circumference of the intervertebral space. Pet. Reply 5 (citing Ex. 1173, 244–245).

Claim 1 recites an implant including a radiopaque marker at least partially positioned in the central region of the implant (i.e., portions of the first and second sidewalls positioned generally centrally between the proximal and distal walls). Claim 16 further recites a radiopaque marker positioned in the central region. Petitioner argues that Baccelli discloses "a third radiopaque marker that is at least partially positioned in said central region." Pet. 22 (citing Ex. 1104, ¶ 41). Baccelli discloses "spikes" that are disposed "about the sagittal midplane" and is "made of a material that is opaque to X-rays." Ex. 1104 ¶¶ 41, 50–51.

Patent Owner argues that "it is not obvious to add the spikes 24 of Baccelli to the PLIF implants of SVS-PR and Telamon because such spikes are unsuitable for PLIF procedures" and that "Baccelli's elongated metal fixation spikes . . . could not be safely inserted in a PLIF procedure . . . because the vertebrae cannot be distract[ed] to the same degree as in an anterior procedure and the spikes would prevent or cause undesirable damage during impaction." PO Resp. 47, 55 (citing Ex. 2020 ¶ 125). Patent Owner's Declarant (Dr. Yuan) testifies that he is of the belief that "the vertebrae cannot be distracted . . . from a posterior approach due to a number of anatomic structures" and that, based on this alleged inability to distract the vertebrae in a posterior approach, "the protruding metal spikes 24 [of

Baccelli] would substantially impair posterior insertion" of an implant. Ex. 2020 ¶ 125. Dr. Yuan, however, does not provide sufficient evidence supporting the contention that the vertebrae "cannot be distracted . . . from a posterior approach." In fact, Dr. Yuan also testifies that during insertion of a spinal implant via a posterior lateral approach, the surgeon may "distract [the vertebrae] probably a couple of millimeters." Ex. 1173, 45. Dr. Yuan does not testify that distracting the vertebrae by "a couple of millimeters" would be insufficient when using "protruding metal spikes."

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art to have combined the teachings of the cited references because various implants "include[] no radiopaque markers in the central region." PO Resp. 46. We are not persuaded by Patent Owner's argument because the question is whether it would have been obvious to one of ordinary skill in the art to combine the cited references and not whether any specific implants on the market contain a radiopaque marker in a central region or not.

Patent Owner argues that "Baccelli . . . describes no reason why radiopaque markers should be added to a PLIF implant [purportedly of SVS or Telamon] in any particular location, let alone in the central region of such PLIF implants" and that Petitioner's Declarant (Dr. Hynes) "never explains why one would add a pair of markers to the central region for such PLIF implants, and certainly does not cite any evidence supporting what he proposes was 'common sense' in 2004 or ever." PO Resp. 48–50 (citing Ex. 1101 ¶ 100; Ex. 2020 ¶¶ 124, 126). We are not persuaded by Patent Owner's argument because, as Petitioner explains, Baccelli discloses radiopaque markers in the central region of a spinal implant.

Patent Owner argues that it would not have been obvious to one of ordinary skill in the art "to add a pair of radiopaque markers to the central region" of an implant because, according to Patent Owner, to do so "would add no meaningful 'additional information' . . . and would increase the likelihood of confusing surgeons." PO Resp. 51 (citing Ex. 2020 ¶¶ 124, 126; Ex. 2013, 163:23 – 164:25). We credit the testimony of Patent Owner's Declarant (Dr. Yuan) that one of ordinary skill in the art would have understood that an implant that "includes two radiopaque markers in the central region [would provide] . . . better align[ment of] the implant" and "also allows a surgeon to see in an anterior-to-posterior x-ray view whether the implant is askew and the degree to which the implant is askew." Ex. 2020 ¶ 64. Given the relative level of skill in the art, we agree with Dr. Yuan that the use of markers to improve x-ray visualization of the alignment of implants, for example, would have been well within the purview of one of ordinary skill in the art at the time of the invention. Hence, we are not persuaded by Patent Owner's contention that "a pair of radiopaque markers to the central region" of an implant would "add no meaningful 'additional information.'"

Also, we are not persuaded by Patent Owner's argument that it would not have been obvious to one of ordinary skill in the art to use a radiopaque marker in the central region of an implant because doing so would confuse surgeons (or those of ordinary skill in the art). Patent Owner's Declarant (Dr. Yuan) testifies that one "complication with using markers . . . is that the implant can have too many of them." Ex. 2020 ¶ 45. Dr. Yuan, however, does not assert or provide sufficient evidence that the specific use of a radiopaque marker in the central region would by "too many" as to result in

confusion or whether such alleged resulting confusion (if any) would be excessive or prohibitive. PO Resp. 54 (citing Ex. 2020 ¶ 45).

Dr. Yuan also testifies that the use of a radiopaque marker in the central region of an implant "could cause problems, including possibly providing confusing imaging information to the surgeon." PO Resp. 54 (citing Ex. 2020 ¶ 124). Dr. Yuan, however, provides insufficient evidence in support of this contention. For example, Dr. Yuan does not provide persuasive evidence supporting the contention that "problems" would arise in the use of a radiopaque marker in the central region of an implant, the nature and extent of any potential "problems," or how any such problems would "confuse" one of ordinary skill in the art and to what extent. Indeed, as previously discussed, Baccelli discloses radiopaque markers in the central region of an implant and does not disclose that one of ordinary skill in the art is confused by such an arrangement.

Patent Owner further argues that Petitioner's Declarant (Dr. Hynes) testifies that it would not have been obvious to one of ordinary skill in the art to have incorporated a radiopaque marker in the central region of an implant because doing so would be "a possible source of confusion." PO Resp. Br. 54 (citing Ex. 2013, 163:23–164:19). However, Dr. Hynes merely testifies that using "the wrong marker" in "the wrong place" may "create[] confusion sometimes." Ex. 2013, 164:11, 12–13. Neither Patent Owner, nor Dr. Hynes, asserts, or demonstrates sufficiently to overcome Petitioner's contrary showing, that the general use of a radiopaque marker in the central region of an implant, as required by the claimed invention, would be using "the wrong marker" that is in "the wrong place." On the contrary, Baccelli discloses the use of such a marker in the central region of an implant, thus

suggesting to one of ordinary skill in the art that such a marker would not have been "wrong" and that the central region would not have been a "wrong place" for such a marker. We are not persuaded by Patent Owner's arguments.

Claim 18 depends from claim 1 and further recites that the maximum lateral width of the implant is approximately 18 mm. Petitioner argues that Michelson discloses an implant "having a maximum lateral width in the range of 14 to 26 mm." Pet. 32 (citing Ex. 1105, 7:26–30). Patent Owner, however, points out that, "Michelson discloses no implant that is longer than 40 mm *and* has a width of 18mm." PO Resp. 57 (citing Ex. 2020 ¶¶ 94, 119). Instead, even assuming that the cited implant of Michelson has a maximum width of 18 mm, as argued by Petitioner, Michelson discloses that the implant measures 12–30 mm in length, which is less than 40 mm, in contrast to the requirement of claim 18 of an implant length that is greater than 40 mm. Nor does Petitioner articulate reasoning with some rational underpinning to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified Michelson's implant to have a length greater than 40 mm.

Petitioner also asserts Michelson incorporates by reference U.S. Patent No. 5,772,661 (Ex. 1046, "Michelson '661") and U.S. Patent No. 5,484,437 (Ex. 1048, "Michelson '437") and argues that "Michelson '661" discloses an implant with a maximum width of 18 mm. *See* Pet. 32. Michelson '661 discloses an implant with a width "in the range of 10 mm to 30 mm." Ex. 1148, 10:31. Even assuming that Michelson '661 discloses an implant with a maximum width of 18 mm (as within the range of 10 mm to 30 mm), Michelson '661 discloses that the length of the implant is "less than

the known transverse width W (side to side) of the vertebrae T7 and T8." Ex. 1148, 10:21–23. Petitioner does not assert or demonstrate sufficiently that the "known transverse width W (side to side) of the vertebrae T7 and T8" (corresponding to the length of the implant) is greater than 40 mm, as required by claim 18. Nor does Petitioner articulate reasoning with some rational underpinning to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

Petitioner also cites U.S. Patent No. 5,484,437 (Ex. 1150, "Michelson '437") as disclosing an implant with a maximum width of 18 mm. *See* Pet. 32–33. Even assuming that Michelson '437 discloses an implant with a maximum width of 18 mm, Petitioner does not assert or demonstrate sufficiently that Michelson '437 also discloses that the implant with a maximum width of 18 mm measures greater than 40 mm in length, as required by claim 18. Nor does Petitioner articulate reasoning with some rational underpinning to support the conclusion that it would have been obvious to one of ordinary skill in the art to have modified the cited implant to have a length greater than 40 mm.

B. Secondary Considerations

Patent Owner argues that "detailed testimony establishes a nexus between NuVasive's CoRoent XL implants and the invention of the '334 patent, and proves the commercial success of the product after NuVasive pioneered the market for lateral, trans-psoas interbody fusion surgeries with the CoRoent XL implant." PO Resp. 59 (citing Ex. 2020, 53–63; Ex. 2030, 7–10, App. A, Section III.D).

We recognize that evidence of secondary considerations must always be considered en route to the determination of obviousness, but its existence alone does not control the conclusion of obviousness. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997). The weight given to evidence of secondary considerations is dependent upon whether there is a nexus between the merits of the claimed invention and the evidence offered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

Even assuming that NuVasive's CoRoent XL implant experienced "commercial success," as Patent Owner asserts, Patent Owner has not demonstrated sufficiently that there is a nexus between the merits of the *claimed* invention and the evidence offered. For example, Patent Owner argues that NuVasive "pioneered the market for lateral, trans-psoas interbody fusion surgeries," (PO Resp. 59) but fails to demonstrate sufficiently that any of the disputed claims recite "lateral, trans-psoas interbody fusion surgeries." We are not persuaded by Patent Owner's arguments.

C. Motion to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude the Declaration of Loic Josse (Ex. 1116, "Josse Declaration"). We did not rely on the Josse Declaration in this decision. Therefore, Patent Owner's motion to exclude is dismissed as moot.

D. Motion for Observation

Patent Owner's observations are directed to the cross-examination testimony of Richard A. Hynes, M.D. (Ex. 38), who was cross-examined after Petitioner filed its Reply. We have considered Patent Owner's

observations and Petitioner's responses in rendering our decision, and have accorded the testimony the appropriate weight as explained above. *See* Obs. 1–9.

Patent Owner also submits observations to the cross-examination testimony of Loic Josse (Ex. 39). As previously discussed, we did not rely on the Josse Declaration in this decision. Therefore, we have not considered Patent Owner's observations directed to the cross-examination testimony of Loic Josse.

ORDER

Petitioner has demonstrated, by a preponderance of the evidence, that claims 1–5, 10, 11, 14–17, and 19–28 are unpatentable over Baccelli, Michelson, and any one of SVS or Telamon under 35 U.S.C. § 103(a). Petitioner has not demonstrated, by a preponderance of the evidence, that claim 18 is unpatentable over Baccelli, Michelson, and any one of SVS or Telamon under 35 U.S.C. § 103(a).

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–5, 10, 11, 14–17, and 19–28 of the '334 patent have been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *dismissed*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2013-00508
Patent 8,187,334 B2

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US008187334B2

(12) **United States Patent**
Curran et al.

(10) **Patent No.: US 8,187,334 B2**
(45) **Date of Patent: May 29, 2012**

(54) **SYSTEM AND METHODS FOR SPINAL FUSION**

(75) Inventors: **Matthew Curran**, Carlsbad, CA (US); **Mark Peterson**, Medford, OR (US)

(73) Assignee: **NuVasive, Inc.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/079,645**

(22) Filed: **Apr. 4, 2011**

(65) **Prior Publication Data**

US 2012/0029641 A1 Feb. 2, 2012

Related U.S. Application Data

(63) Continuation of application No. 11/093,409, filed on Mar. 29, 2005, now Pat. No. 7,918,891.

(60) Provisional application No. 60/557,536, filed on Mar. 29, 2004.

(51) **Int. Cl.**
A61F 2/44 (2006.01)

(52) **U.S. Cl.** **623/17.16**

(58) **Field of Classification Search** 623/17.11–17.16
See application file for complete search history.

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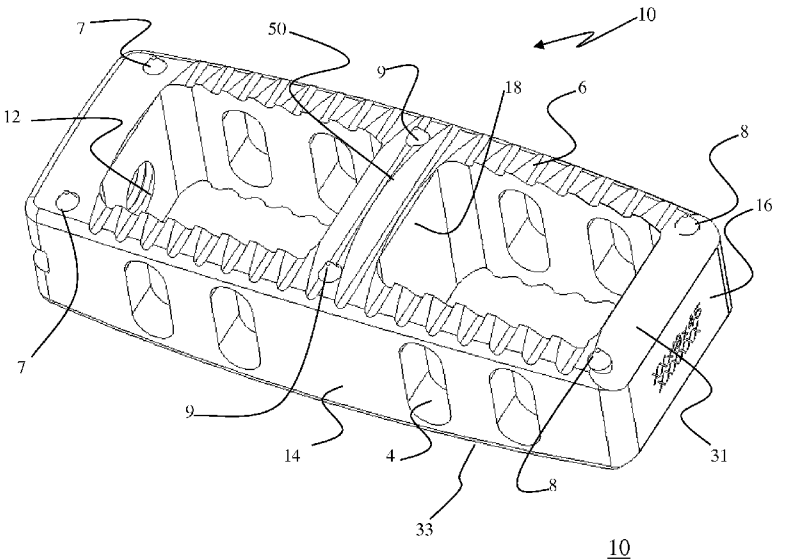
Assistant Examiner — Stuart S Bray
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

A system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

28 Claims, 20 Drawing Sheets



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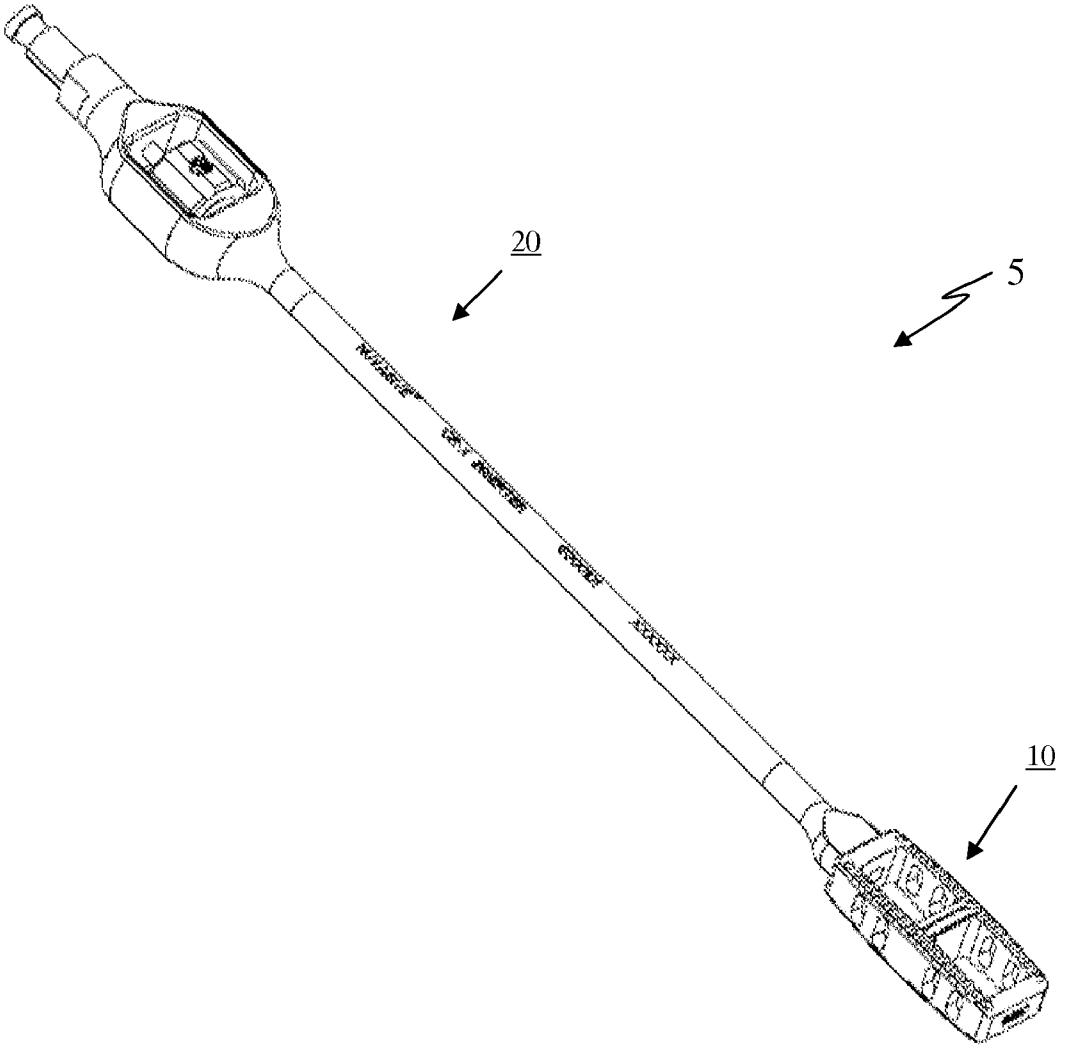

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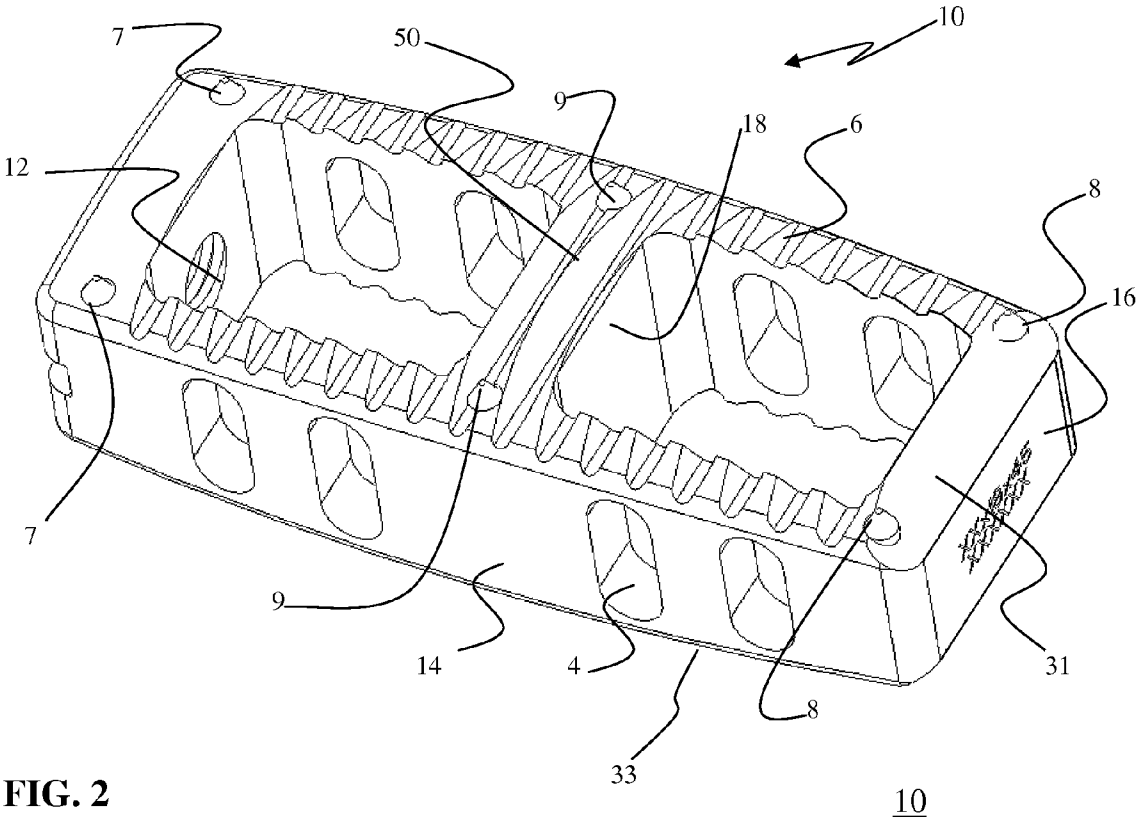

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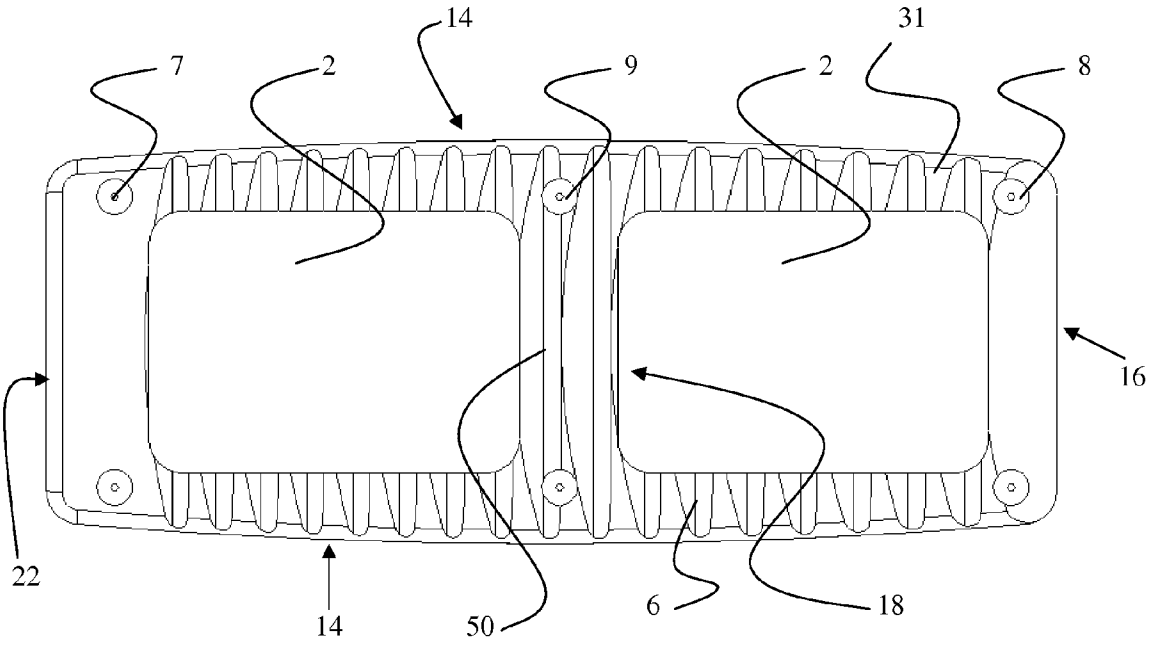

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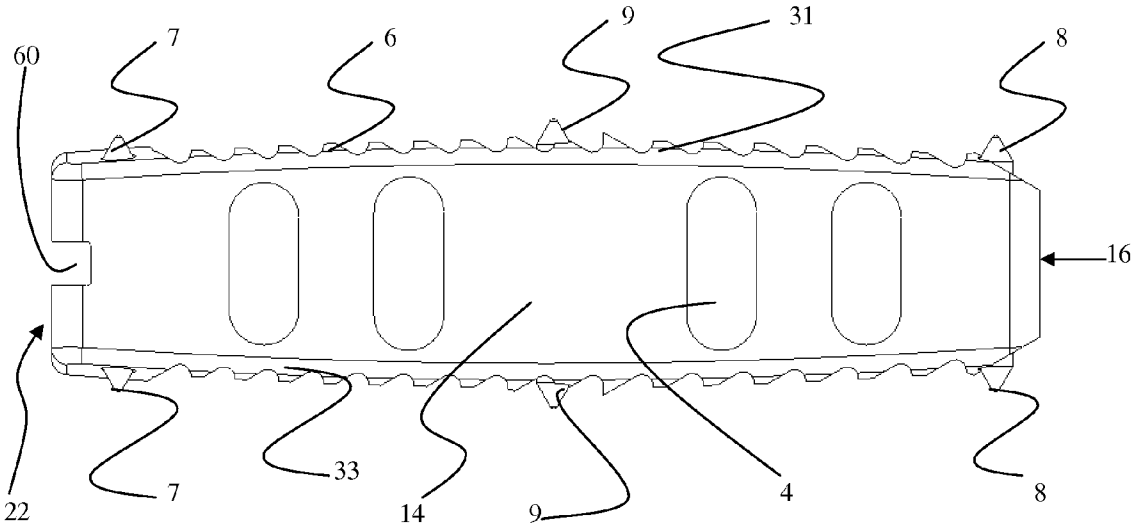

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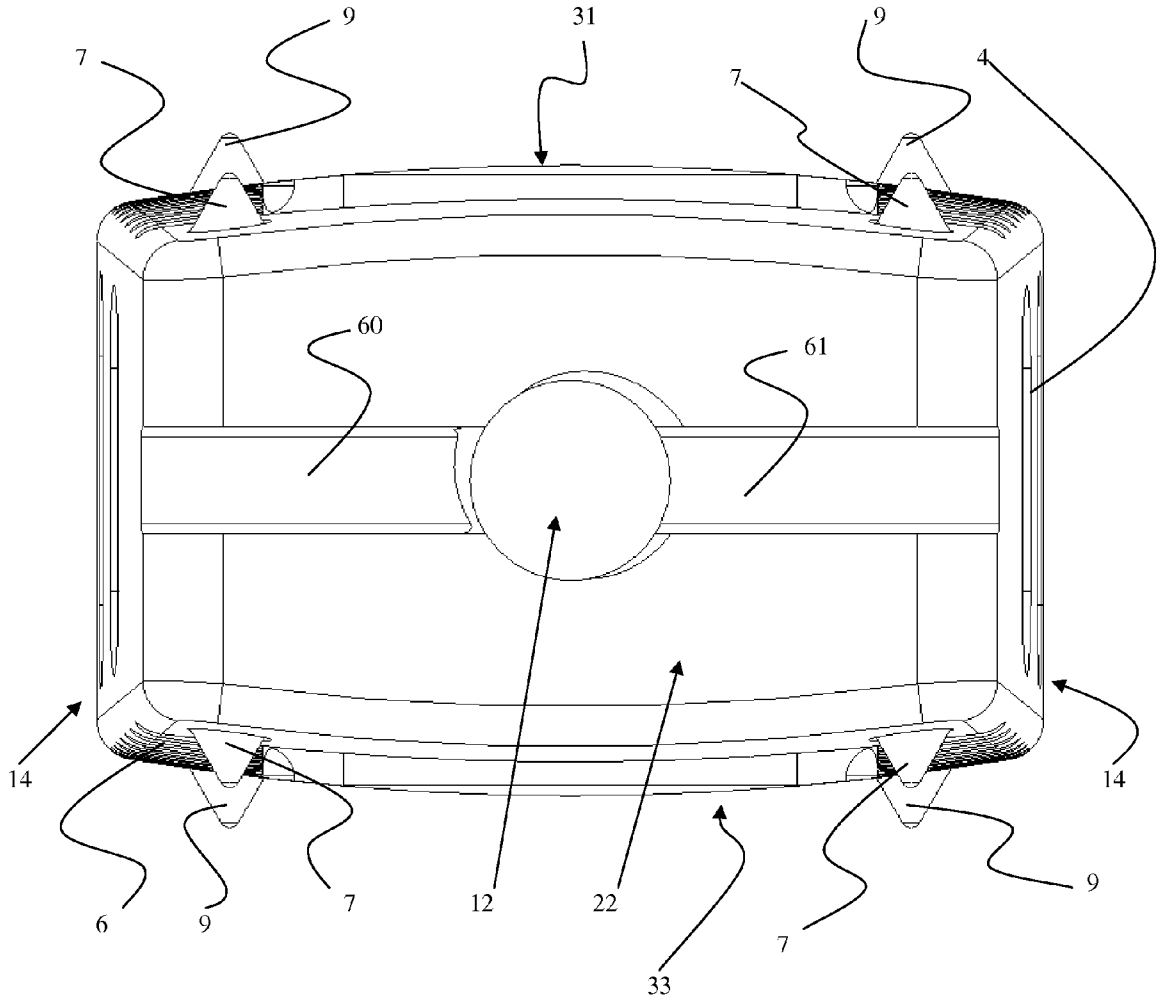

FIG. 5

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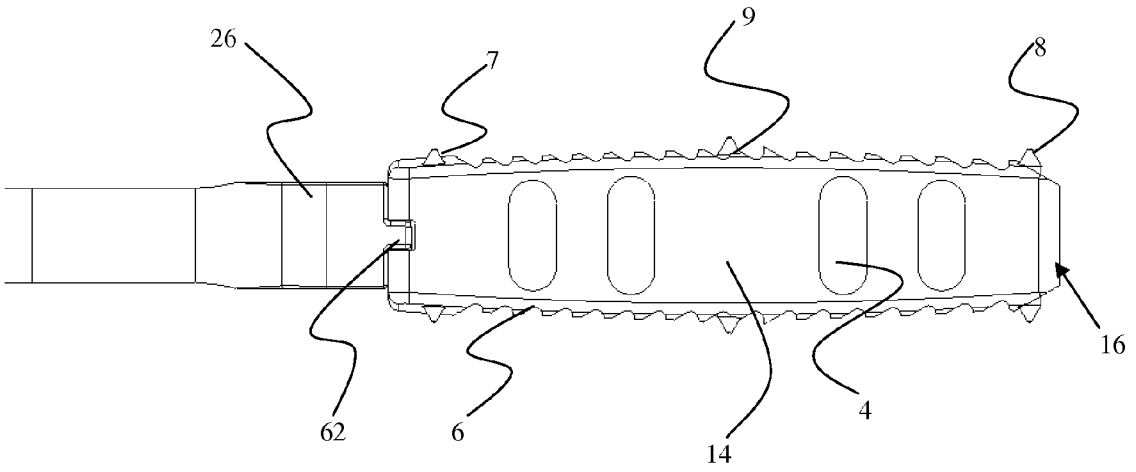

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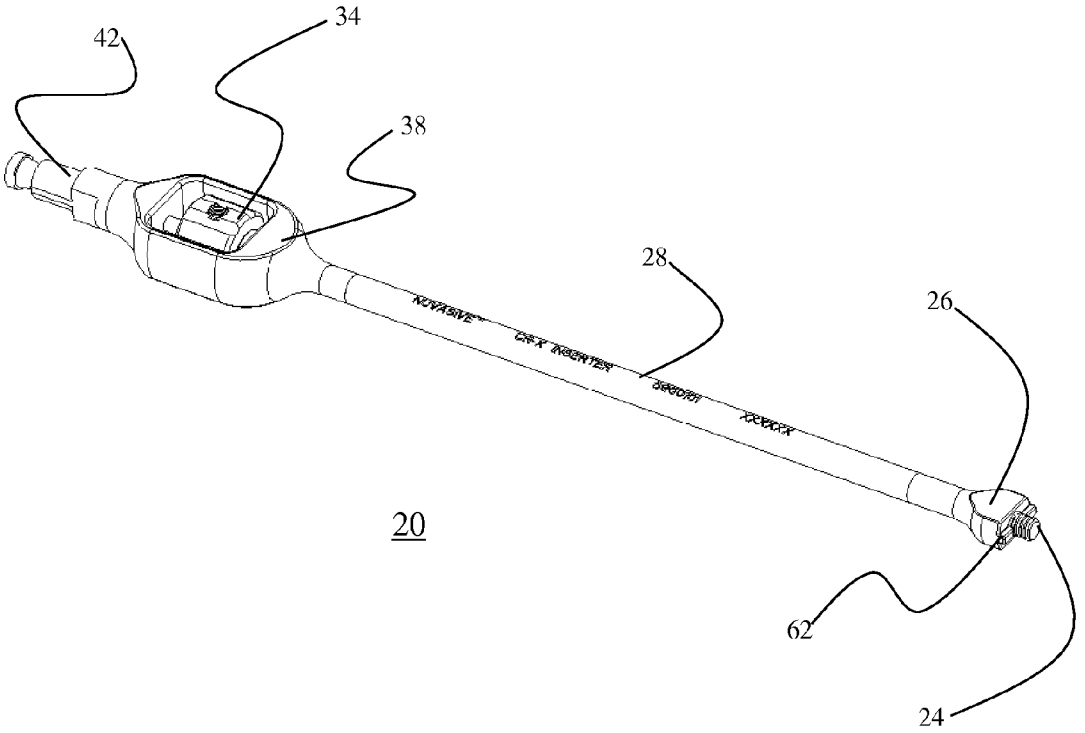

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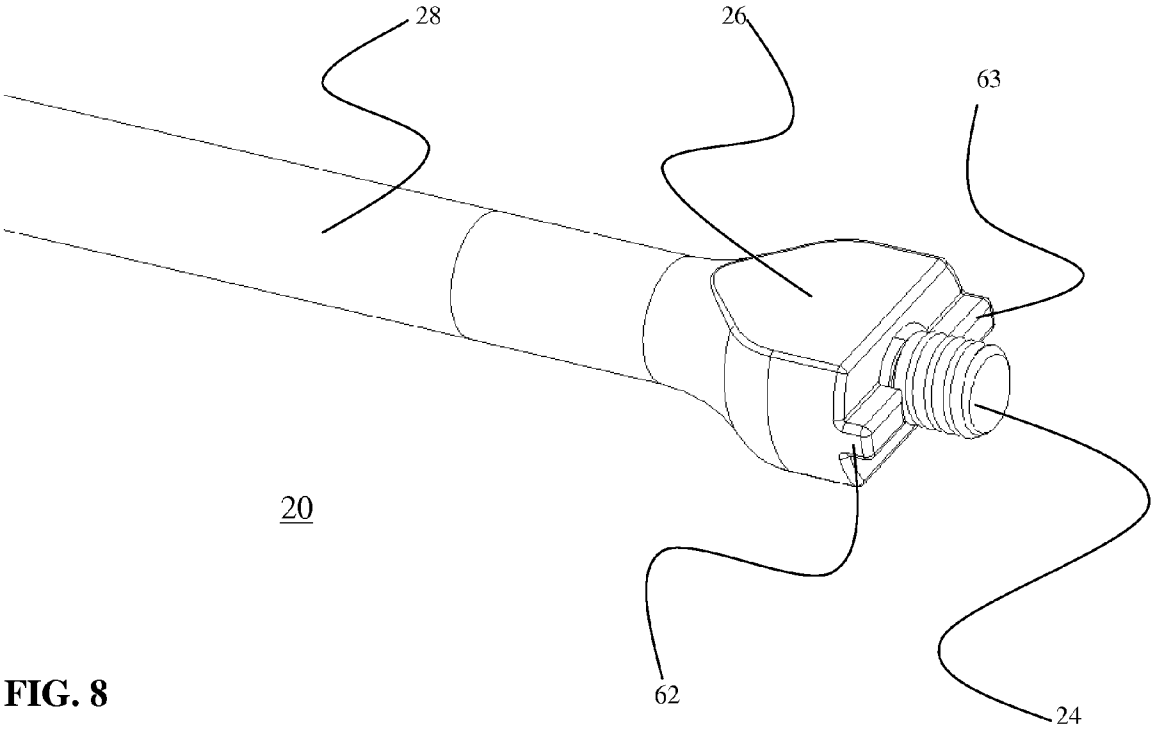

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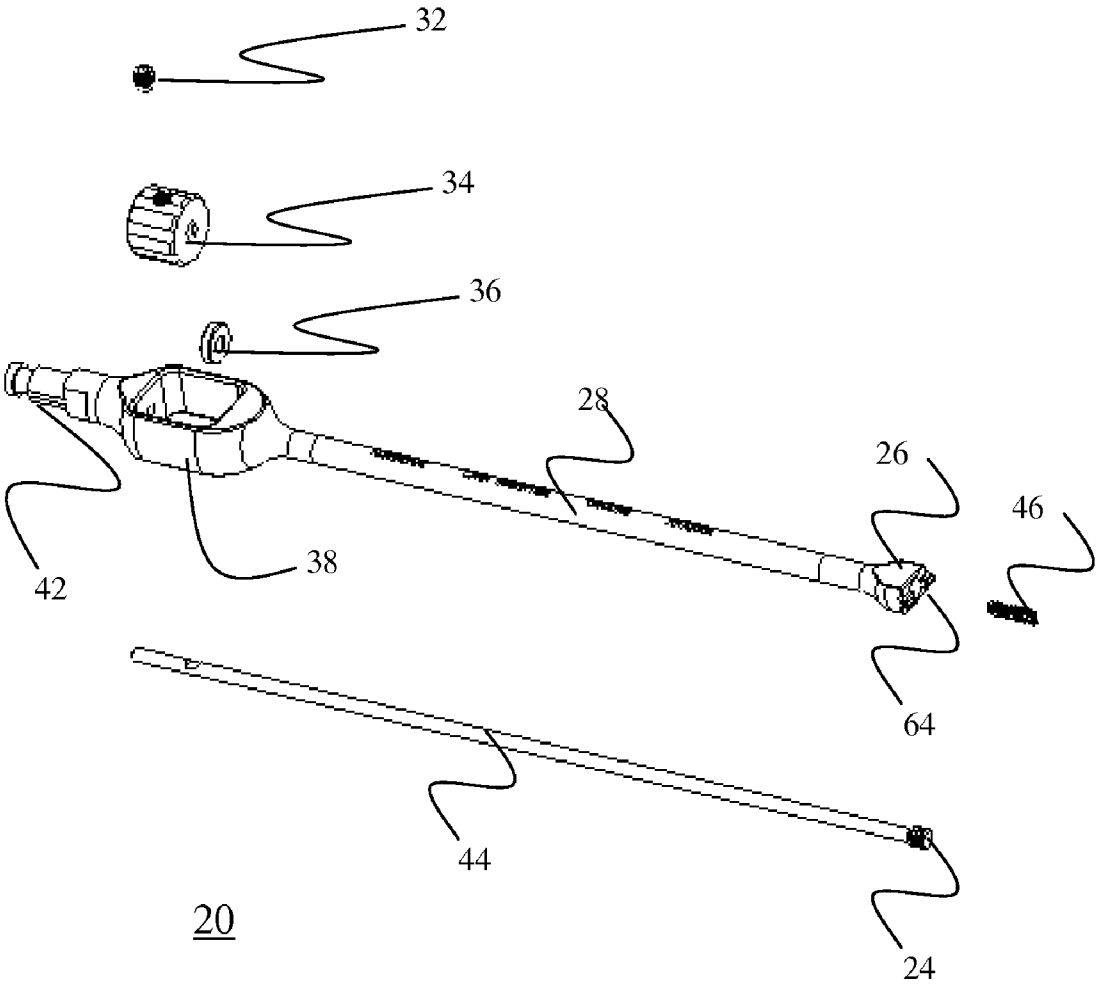

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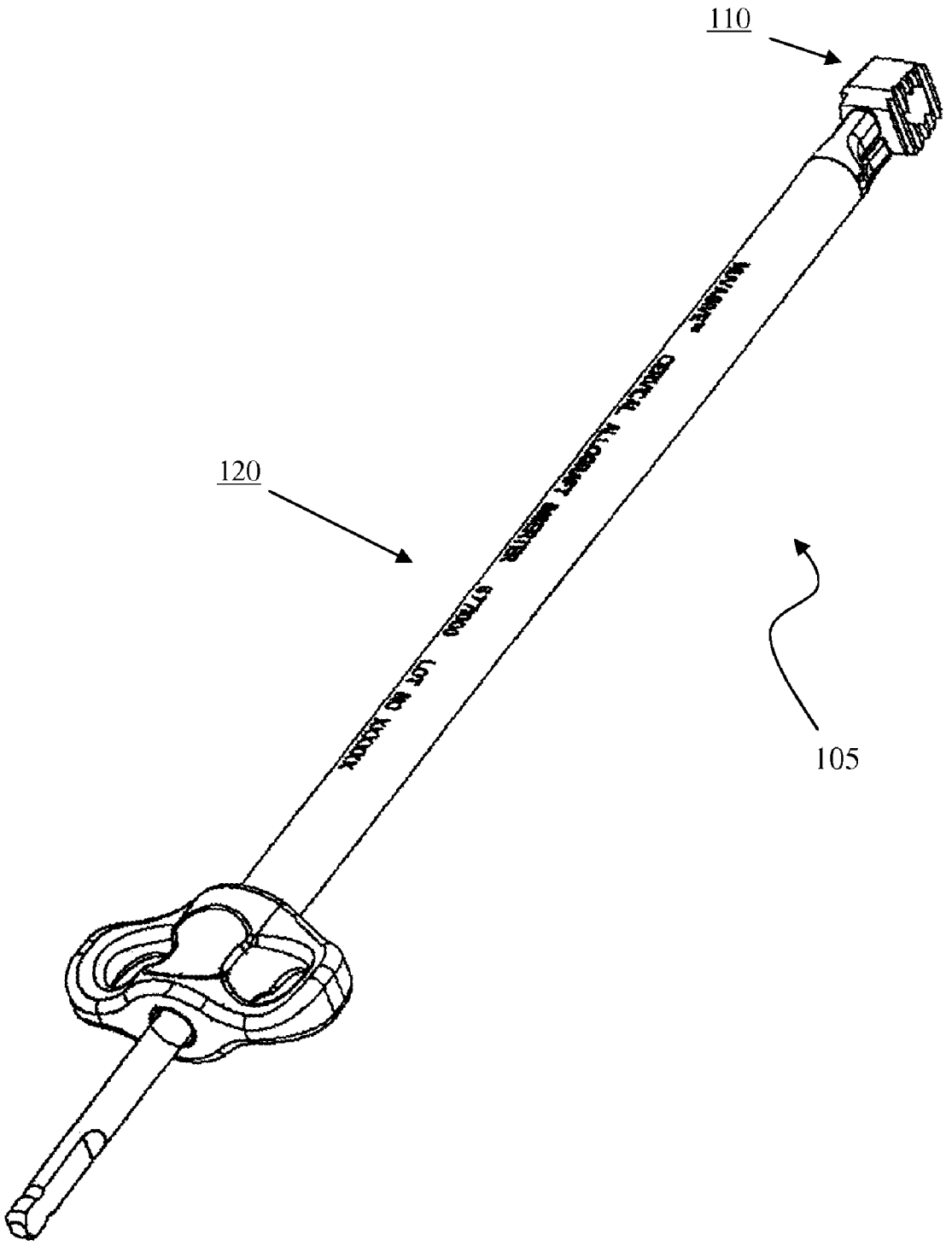

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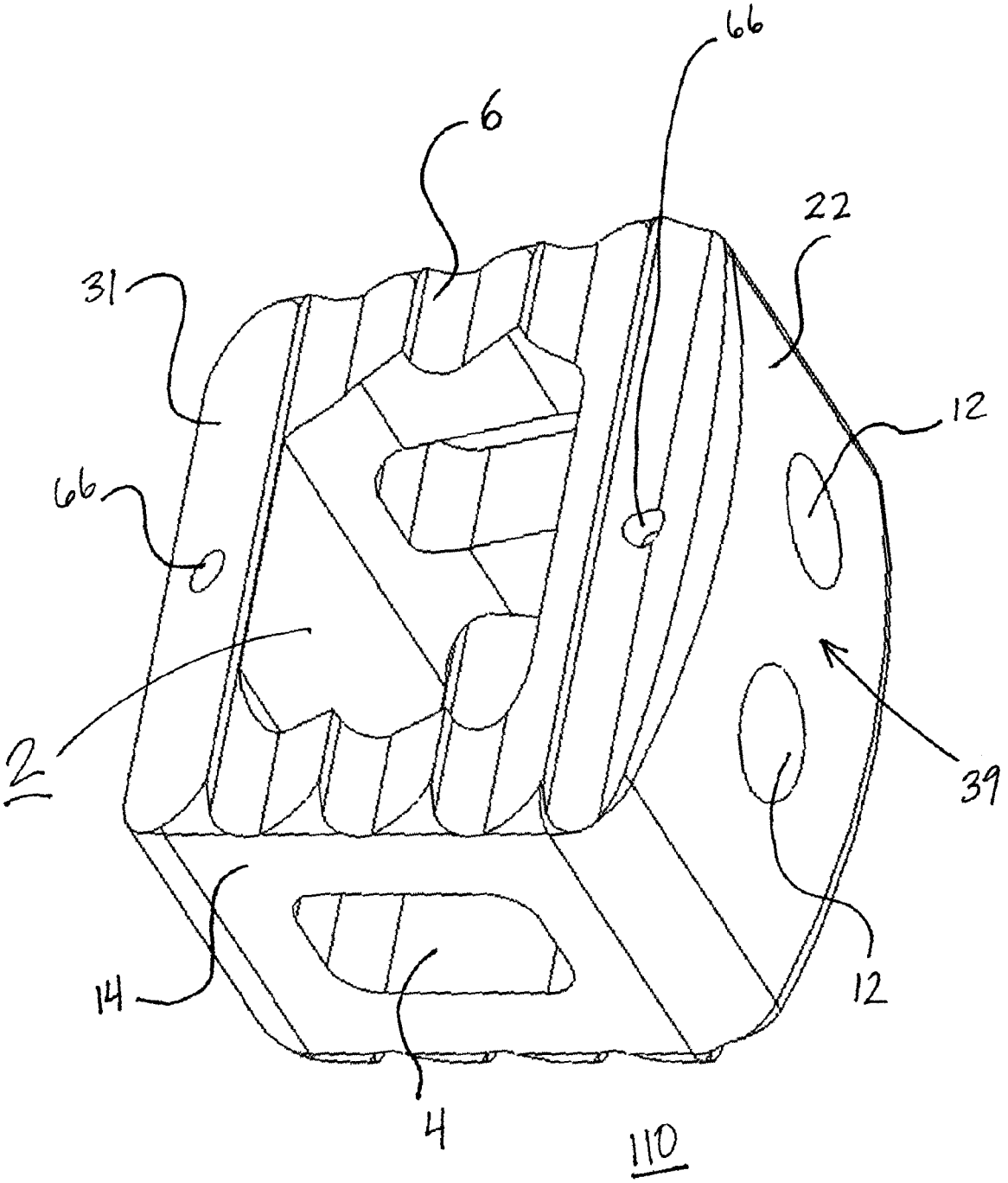
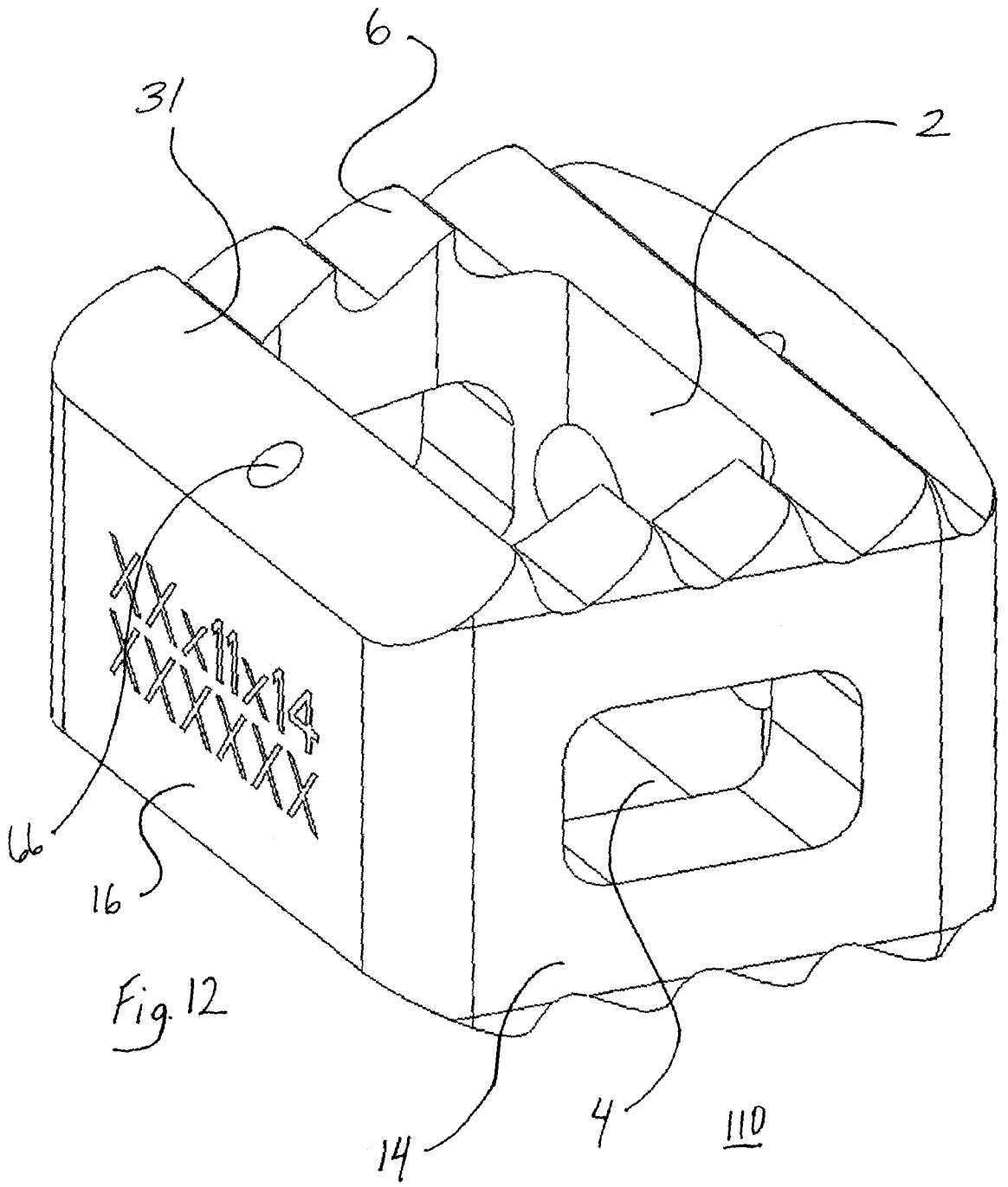


Fig. 11



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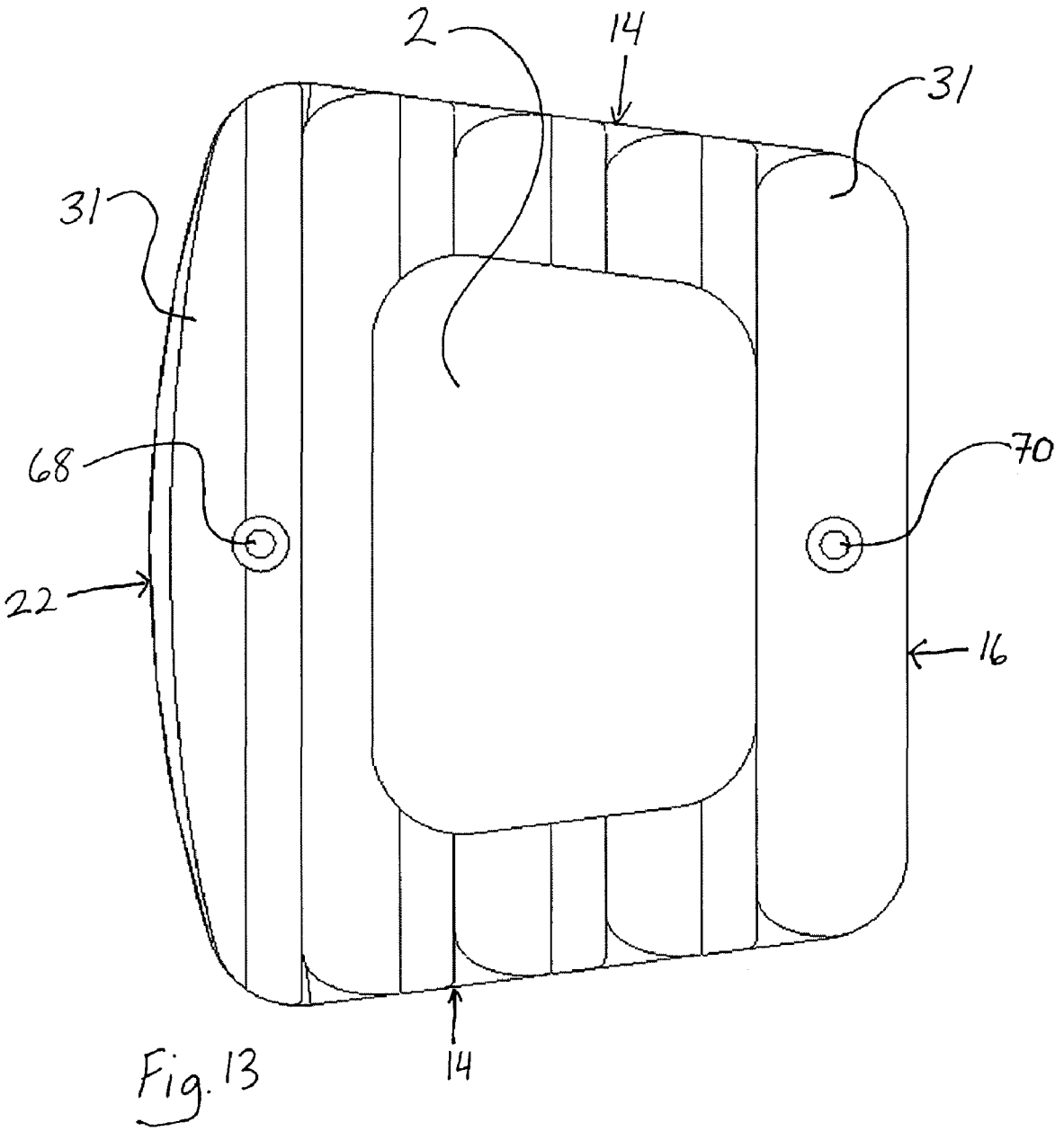

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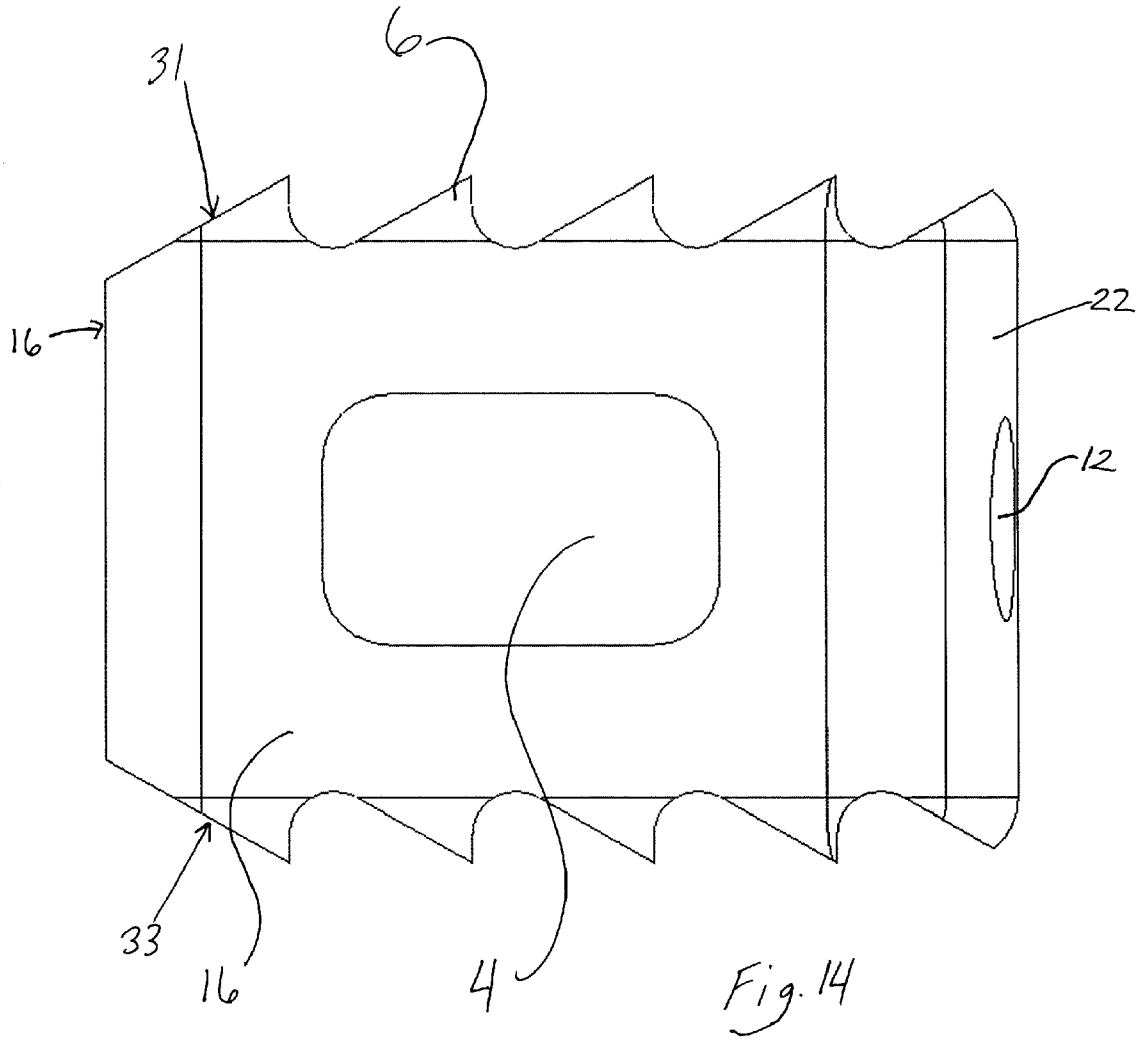
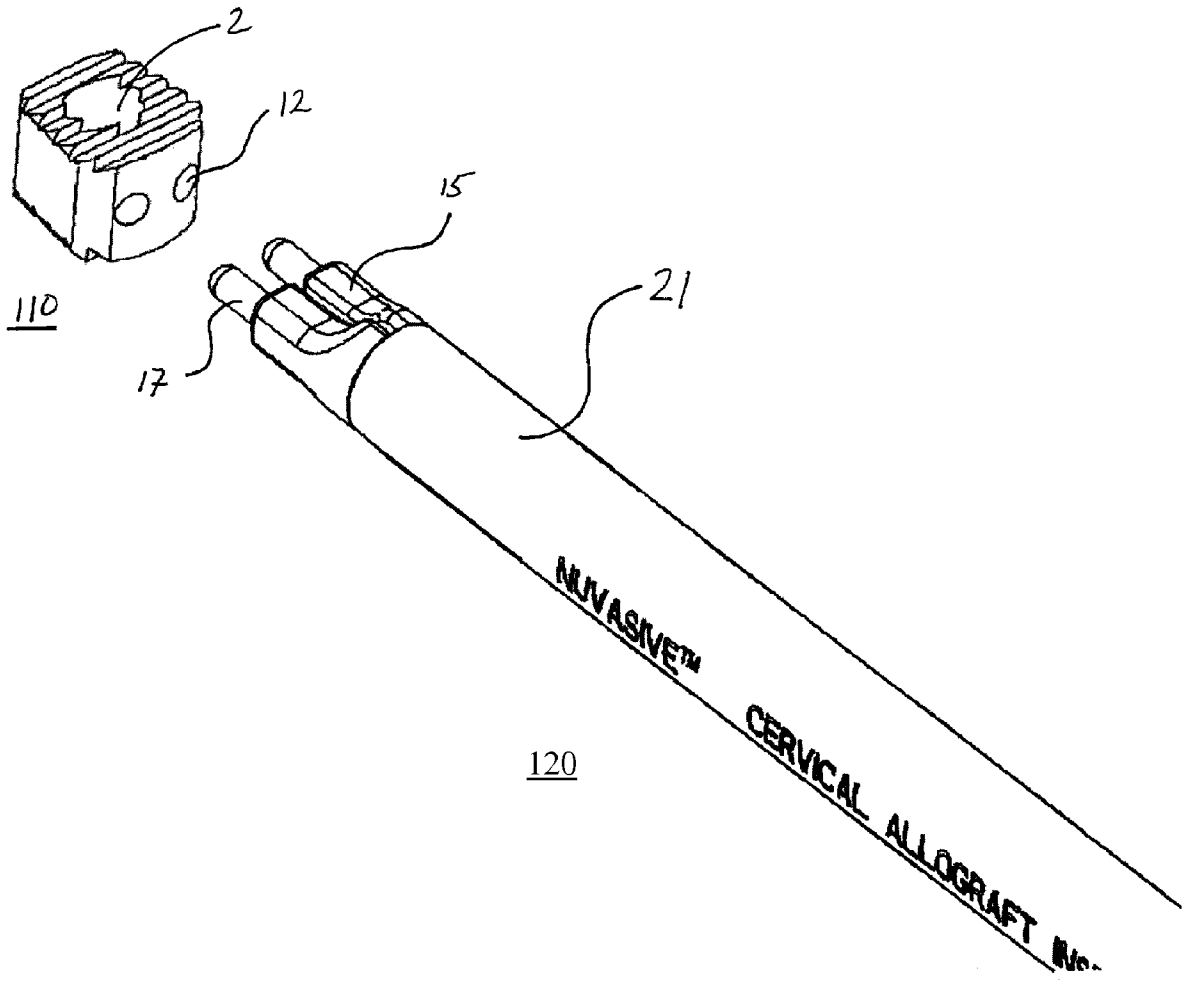


Fig. 14



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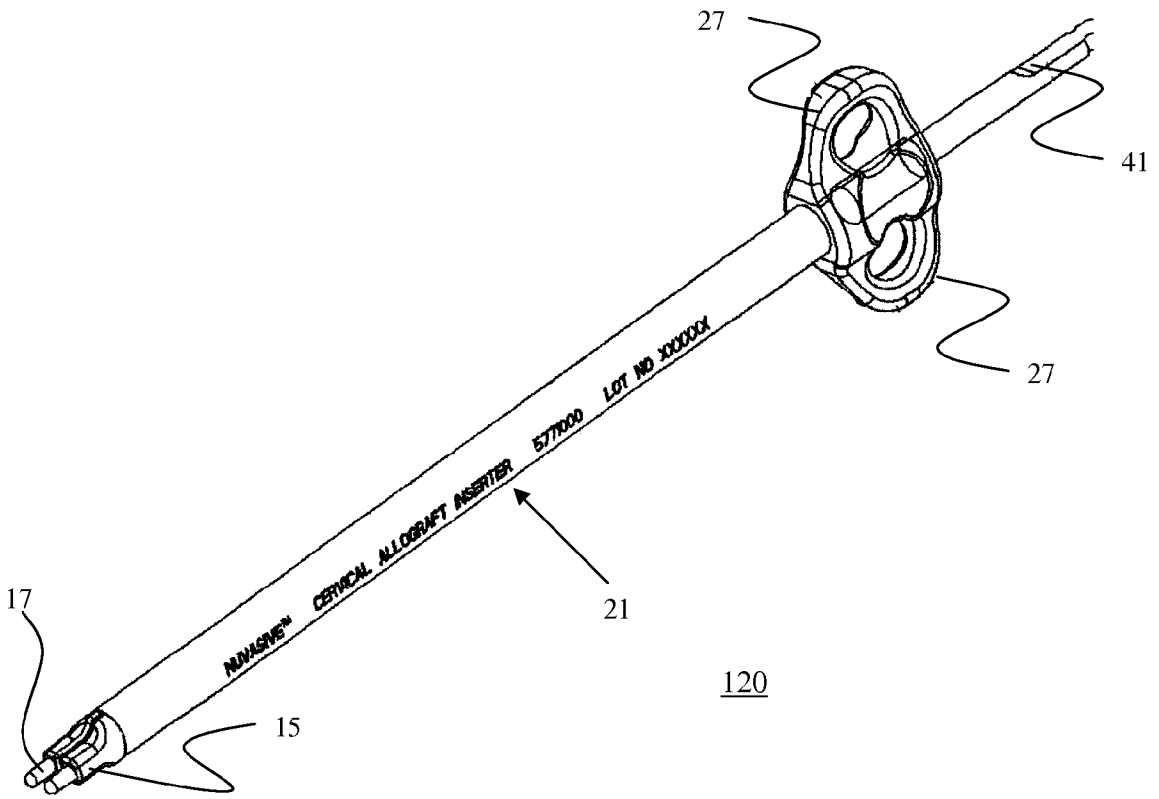

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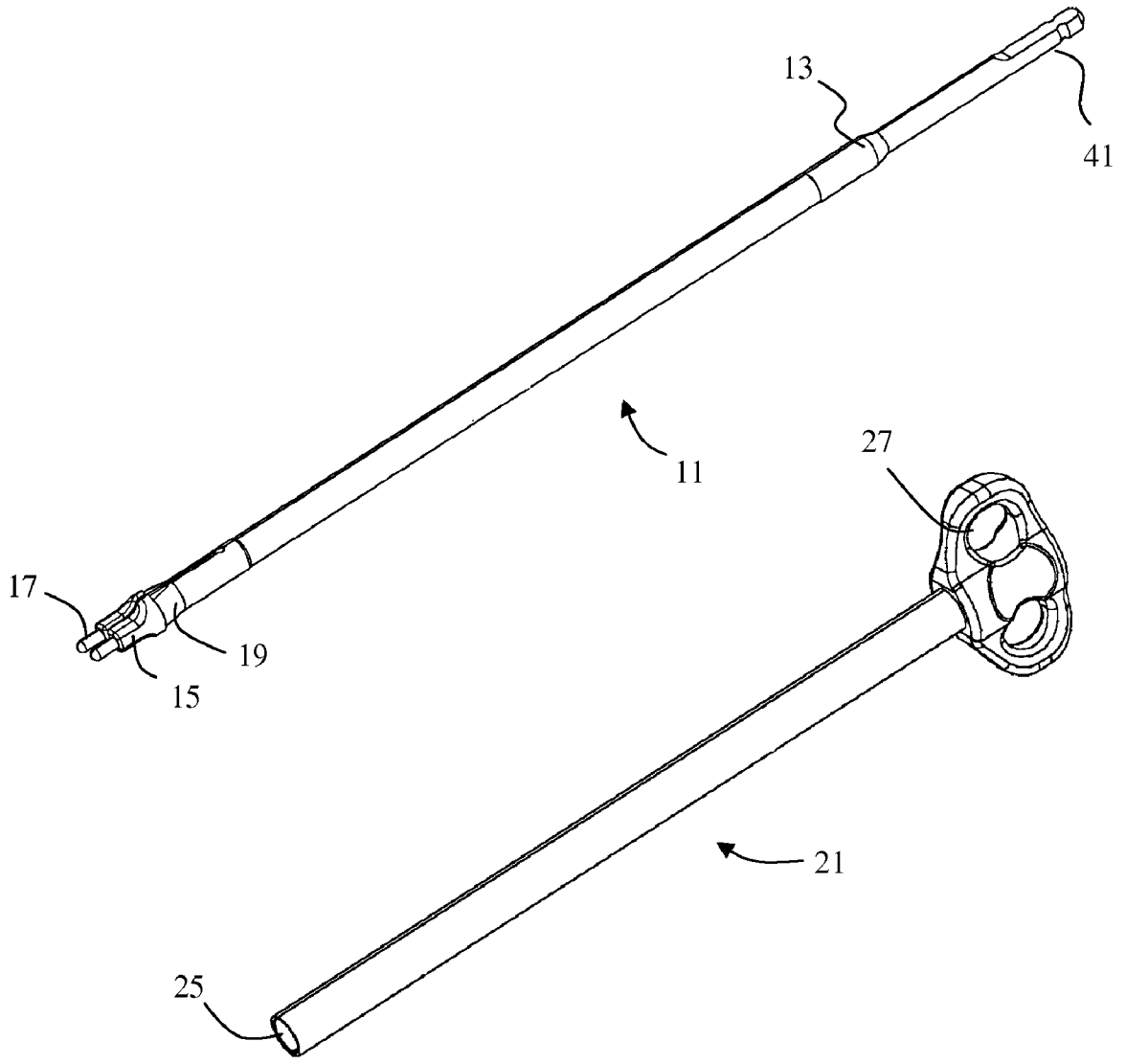

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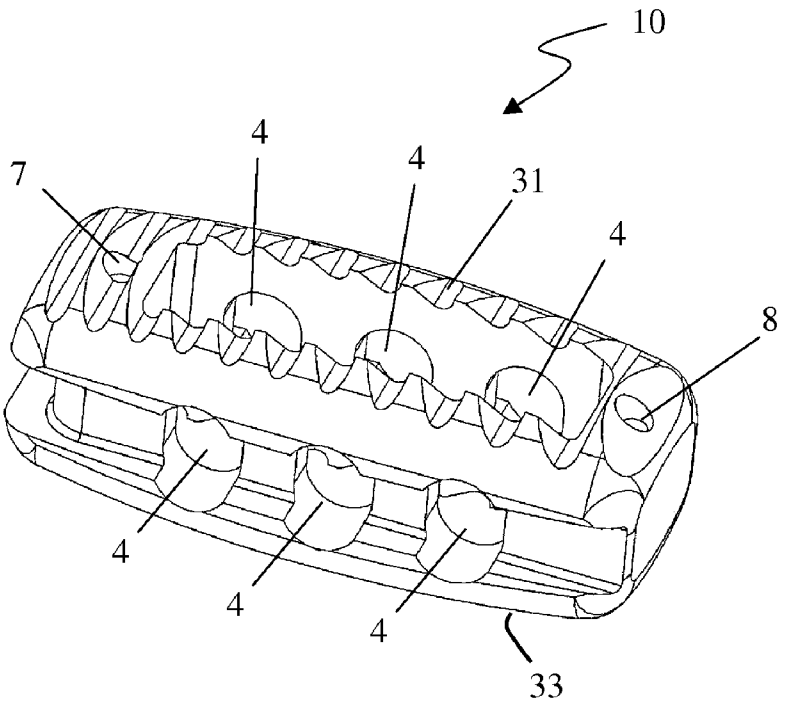


FIG. 18

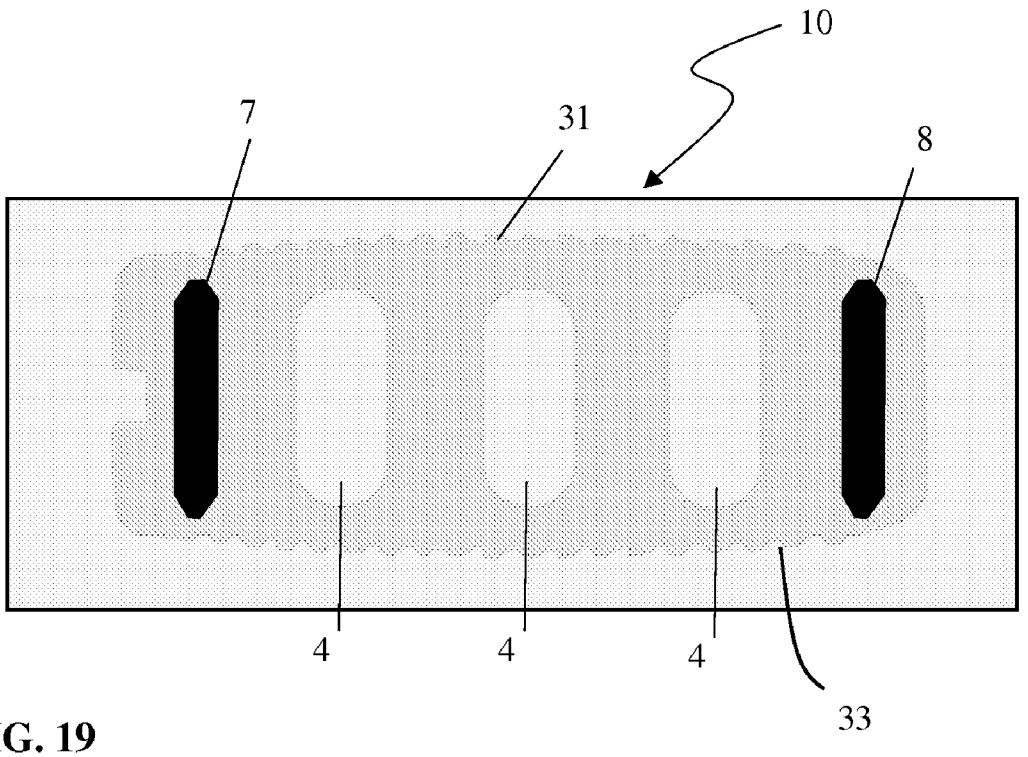
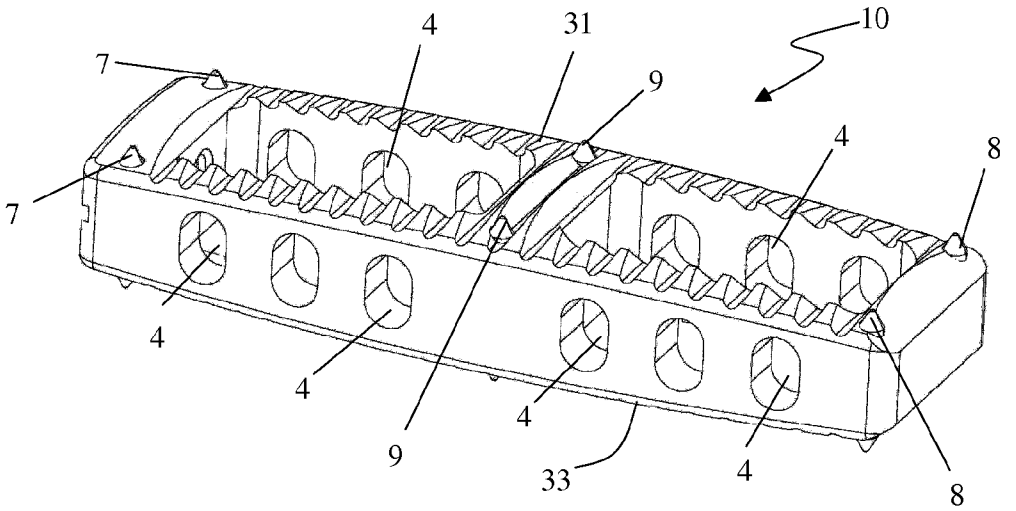


FIG. 19

FIG. 20



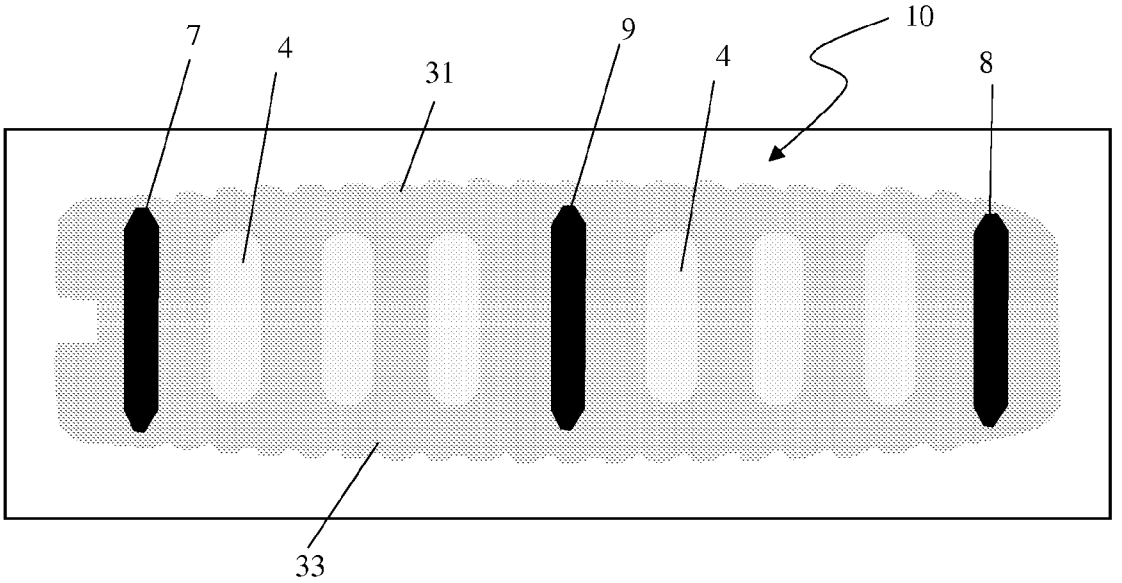


FIG. 21

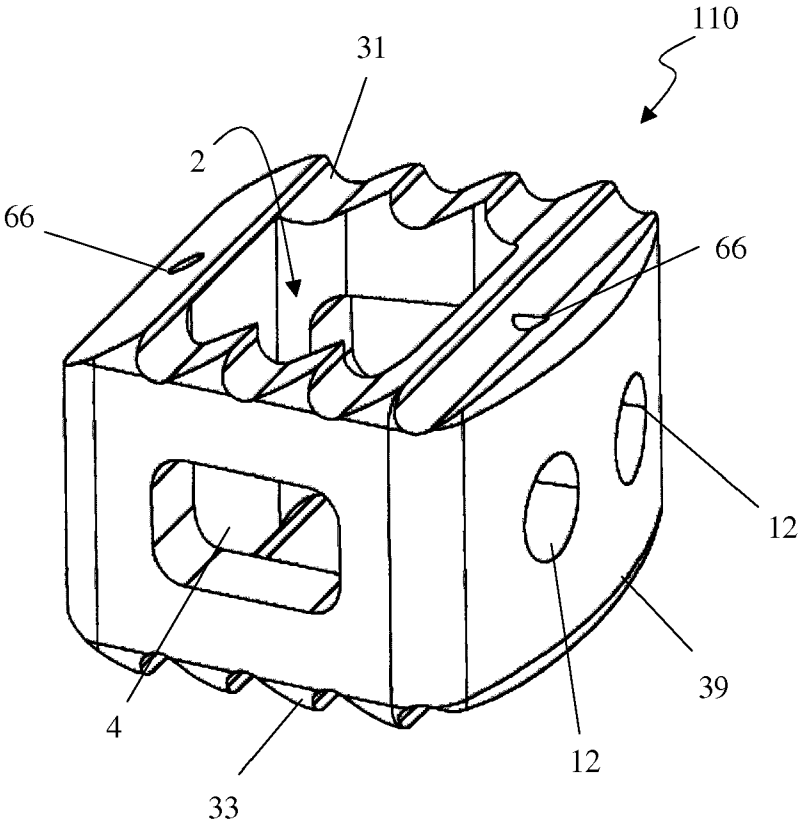


FIG. 22

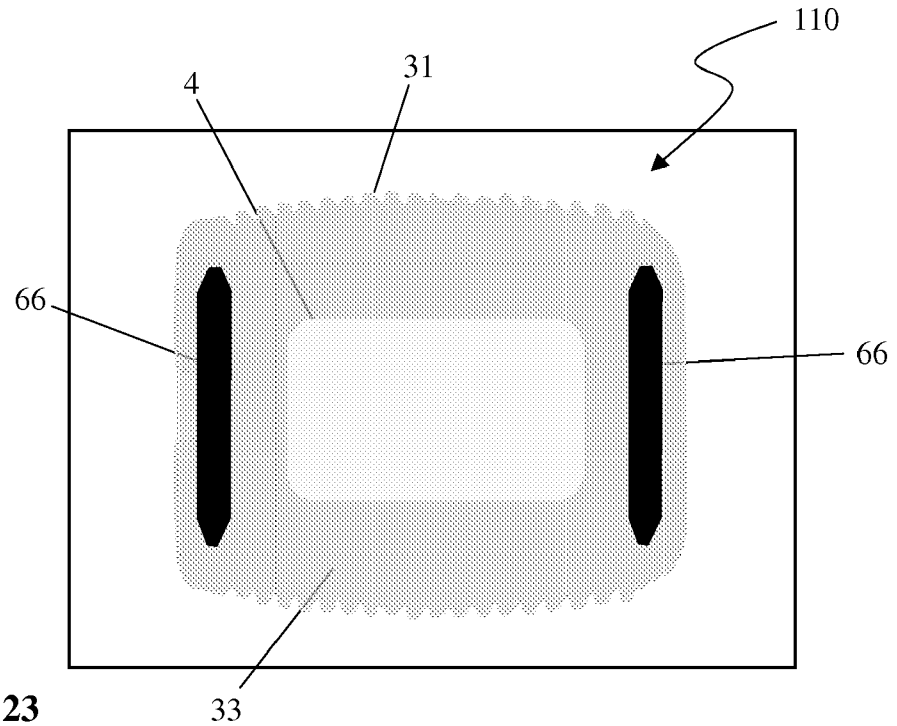


FIG. 23

SYSTEM AND METHODS FOR SPINAL FUSION

CROSS-REFERENCE TO RELATED APPLICATION

This application is continuation of U.S. patent application Ser. No. 11/093,409 filed Mar. 29, 2005 now U.S. Pat. No. 7,918,891, which claims the benefit of the filing date under 35 USC 119(e) of U.S. Provisional Application entitled "Systems and Methods for Spinal Fusion," Ser. No. 60/557,536 filed Mar. 29, 2004, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to spinal surgery and, more particularly, to a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

II. Discussion of the Prior Art

Currently there are nearly 500,000 spine lumbar and cervical fusion procedures performed each year in the United States. Such procedures are commonly performed to correct problems, such as chronic back or neck pain, which result from degenerated intervertebral discs or trauma. Generally, spinal fusion procedures involve removing some or all of the diseased or damaged disc, and inserting one or more intervertebral implants into the resulting disc space. Introducing the intervertebral implant serves to restore the height between adjacent vertebrae ("disc height"), which reduces if not eliminates neural impingement commonly associated with a damaged or diseased disc.

Autologous bone grafts are widely used intervertebral implant for lumbar fusion. Autologous bone grafts are obtained by harvesting a section of bone from the iliac crest of the patient and thereafter implanting the article of autologous bone graft to effect fusion. While generally effective, the use of autologous bone grafts suffers certain drawbacks. A primary drawback is the morbidity associated with harvesting the autologous graft from the patient's iliac crest. Another related drawback is the added surgical time required to perform the bone-harvesting.

Allograft bone grafts have been employed with increased regularity in an effort to overcome the drawbacks of autologous bone grafts. Allograft bone grafts are harvested from cadaveric specimens, machined, and sterilized for implantation. While allograft bone grafts eliminate the morbidity associated with iliac crest bone harvesting, as well as decrease the overall surgical time, they still suffer certain drawbacks. A primary drawback is supply constraint, in that the tissue banks that process and produce allograft bone implants find it difficult to forecast allograft given the inherent challenges in forecasting the receipt of cadavers. Another related drawback is that it is difficult to manufacture the allograft with consistent shape and strength characteristics given the variation from cadaver to cadaver.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

SUMMARY OF THE INVENTION

The present invention overcomes the drawbacks of the prior art by providing a spinal fusion system and related

methods involving the use of a spinal fusion implant of non-bone construction. The non-bone construction of the spinal fusion implant of the present invention overcomes the drawbacks of the prior art in that it is not supply limited (as with allograft) and does not require harvesting bone from the patient (as with autograft). The spinal fusion implant of the present invention may be comprised of any suitable non-bone composition, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)), ceramic, metal or any combination of these materials.

The spinal fusion implant of the present invention may be provided in any number of suitable shapes and sizes depending upon the particular surgical procedure or need. The spinal fusion implant of the present invention may be dimensioned for use in the cervical and/or lumbar spine without departing from the scope of the present invention. For lumbar fusion, the spinal fusion implant of the present invention may be dimensioned, by way of example only, having a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm. For cervical fusion, the spinal fusion implant of the present invention may be dimensioned, by way of example only, having a width about 11 mm, a height ranging between 5 and 12 mm, and a length about 14 mm.

The spinal fusion implant of the present invention may be provided with any number of additional features for promoting fusion, such as apertures extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant of the present invention. Such fusion-promoting apertures may be dimensioned to receive any number of suitable osteoinductive agents, including but not limited to bone morphogenic protein (BMP) and bio-resorbable polymers, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers. The spinal fusion implant of the present invention is preferably equipped with one or more lateral openings which aid it provides in visualization at the time of implantation and at subsequent clinical evaluations.

The spinal fusion implant of the present invention may be provided with any number of suitable anti-migration features to prevent spinal fusion implant from migrating or moving from the disc space after implantation. Suitable anti-migration features may include, but are not necessarily limited to, angled teeth formed along the upper and/or lower surfaces of the spinal fusion implant and/or spike elements disposed partially within and partially outside the upper and/or lower surfaces of the spinal fusion implant. Such anti-migration features provide the additional benefit of increasing the overall surface area between the spinal fusion implant of the present invention and the adjacent vertebrae, which promotes overall bone fusion rates.

The spinal fusion implant of the present invention may be provided with any number of features for enhancing the visualization of the implant during and/or after implantation into a spinal target site. According to one aspect of the present invention, such visualization enhancement features may take the form of the spike elements used for anti-migration, which may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces of the implant. The spike elements may each comprise a unitary element extending through upper and

lower surfaces or, alternatively, each spike element may comprise a shorter element which only extends through a single surface (that is, does not extend through the entire height of the implant). In any event, when the spike elements are provided having radiodense characteristics and the implant is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant during implantation and/or the placement of the implant after implantation.

The spinal implant of the present invention may be introduced into a spinal target site through the use of any of a variety of suitable instruments having the capability to releasably engage the spinal implant. In a preferred embodiment, The insertion instrument permits quick, direct, accurate placement of the spinal implant of the present invention into the intervertebral space. According to one embodiment, the insertion instrument includes a threaded engagement element dimensioned to threadably engage into a receiving aperture formed in the spinal fusion implant of the present invention. According to another embodiment, the insertion instrument includes an elongate fork member and a generally tubular lock member.

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. **1** is a perspective view of a spinal fusion system of the present invention, including a lumbar fusion implant releasably coupled to an insertion instrument according to one embodiment of the present invention;

FIG. **2** is a perspective view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the side walls, and a variety of anti-migration features according to one embodiment of the present invention;

FIG. **3** is a top view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) the fusion apertures and the anti-migration features according to one embodiment of the present invention;

FIG. **4** is a side view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) the visualization apertures, the anti-migration feature, and a receiving aperture for releasably engaging the insertion instrument of FIG. **1** according to one embodiment of the present invention;

FIG. **5** is an end view of the lumbar fusion implant of FIG. **1**, illustrating (among other things) the receiving aperture formed in the proximal end, the anti-migration features, and the visualization apertures according to one embodiment of the present invention;

FIG. **6** is an enlarged side view of the lumbar fusion implant of FIG. **1** releasably coupled to the distal end of the insertion instrument of FIG. **1** according to one embodiment of the present invention;

FIG. **7** is a perspective view of the insertion instrument of FIG. **1** in a fully assembled form according to one embodiment of the present invention;

FIG. **8** is an enlarged perspective view of the distal region of the insertion instrument of FIG. **1** according to one embodiment of the present invention;

FIG. **9** is a perspective exploded view of the insertion instrument of FIG. **1**, illustrating the component parts of the insertion instrument according to one embodiment of the present invention;

FIG. **10** is a perspective view of a spinal fusion system of the present invention, including a cervical fusion implant releasably coupled to a cervical insertion instrument according to one embodiment of the present invention;

FIG. **11** is a perspective view of the proximal side of the cervical fusion implant of FIG. **10**, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the lateral walls, a plurality of receiving apertures, and a variety of anti-migration features according to one embodiment of the present invention;

FIG. **12** is a perspective view of the distal side cervical fusion implant of FIG. **10**, illustrating (among other things) the visualization apertures and anti-migration features;

FIG. **13** is a top view of the cervical fusion implant of FIG. **10**, illustrating (among other things) the fusion apertures and anti-migration features according to one embodiment of the present invention;

FIG. **14** is a side view of the cervical fusion implant of FIG. **10**, illustrating (among other things) the visualization apertures, the anti-migration features, and one of two receiving apertures provided in the proximal end for releasably engaging the cervical insertion instrument of FIG. **10** according to one embodiment of the present invention;

FIG. **15** is a perspective view of the cervical fusion implant of the present invention just prior to attachment to the cervical insertion device according to one embodiment of the present invention;

FIG. **16** is a perspective view of the insertion instrument of FIG. **10** in a fully assembled form according to one embodiment of the present invention;

FIG. **17** is a perspective exploded view of the insertion instrument of FIG. **10**, illustrating the component parts of the insertion instrument according to one embodiment of the present invention.

FIGS. **18** and **19** are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a lumbar fusion implant according to one embodiment of the present invention;

FIGS. **20** and **21** are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a lumbar fusion implant according to one embodiment of the present invention; and

FIGS. **22** and **23** are perspective and side views, respectively, illustrating the "enhanced visualization" feature of the present invention as employed within a cervical fusion implant according to one embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of

ordinary skill in the art having the benefit of this disclosure. The system to facilitate bone fusion and related methods disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

FIG. **1** illustrates, by way of example only, a spinal fusion system **5** for performing spinal fusion between adjacent lumbar vertebrae, including an exemplary spinal fusion implant **10** and an exemplary insertion instrument **20** provided in accordance with the present invention. The spinal fusion implant **10** may be comprised of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant **10** of the present invention may be dimensioned, by way of example only, having a width ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 25 and 45 mm.

As will be described in detail below, the insertion instrument **20** is configured to releasably maintain the exemplary spinal fusion implant **10** in the proper orientation during insertion into a lumbar disc space and thereafter release to deposit the implant **10**. The exemplary spinal fusion implant **10**, having been deposited in the disc space, facilitates spinal fusion over time by maintaining a restored disc height as natural bone growth occurs through and/or past the implant **10**, resulting in the formation of a boney bridge extending between the adjacent vertebral bodies. The implant **10** is particularly suited for introduction into the disc space via a lateral (trans-psoas) approach to the spine, but may be introduced in any of a variety of approaches, such as posterior, anterior, antero-lateral, and postero-lateral, without departing from the scope of the present invention (depending upon the sizing of the implant **10**).

The spinal fusion implant **10** of the present invention may be provided with any number of additional features for promoting fusion, such as apertures **2** extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant **10**. According to a still further aspect of the present invention, this fusion may be facilitated or augmented by introducing or positioning various osteoinductive materials within the apertures **2** and/or adjacent to the spinal fusion implant **10**. Such osteoinductive materials may be introduced before, during, or after the insertion of the exemplary spinal fusion implant **10**, and may include (but are not necessarily limited to) autologous bone harvested from the patient receiving the spinal fusion implant **10**, bone allograft, bone xenograft, any number of non-bone implants (e.g. ceramic, metallic, polymer), bone morphogenic protein, and bio-resorbable compositions, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers.

The spinal fusion implant **10** of the present invention is preferably equipped with one or more visualization apertures **4** situated along the lateral sides, which aid in visualization at the time of implantation and at subsequent clinical evaluations. More specifically, based on the generally radiolucent nature of the implant **10**, the visualization apertures **4** provide the ability to visualize the interior of the implant **10** during X-ray and/or other suitable imaging techniques which are undertaken from the side (or "lateral") perspective of the implant **10**. If fusion has taken place, the visualization apertures **4** will provide a method for the surgeon to make follow up assessments as to the degree of fusion without any visual interference from the spinal fusion implant **10**. Further, the visualization apertures **4** will provide an avenue for cellular migration to the exterior of the spinal fusion implant **10**. Thus the spinal fusion implant **10** will serve as additional scaffolding for bone fusion on the exterior of the spinal fusion implant **10**.

FIGS. **2-5** depict various embodiments of the exemplary spinal fusion implant **10**. Some common attributes are shared among the various embodiments. More specifically, each spinal fusion implant **10** has a top surface **31**, a bottom surface **33**, lateral sides **14**, a proximal side **22**, and a distal side **16**. In one embodiment, the top and bottom surfaces **31**, **33** are generally parallel. It can be appreciated by one skilled in the art that although the surfaces **31**, **33** are generally parallel to one another, they may be provided in any number of suitable shapes, including but not limited to concave and/or convex. When provided as convex shapes, the top and bottom surfaces **31**, **33** may better match the natural contours of the vertebral end plates. Although not shown, it will be appreciated that the top and bottom surfaces **31**, **33** may be angled relative to one another to better match the natural lordosis of the lumbar and cervical spine or the natural kyphosis of the thoracic spine

The exemplary spinal fusion implant **10** also preferably includes anti-migration features designed to increase the friction between the spinal fusion implant **10** and the adjacent contacting surfaces of the vertebral bodies so as to prohibit migration of the spinal fusion implant **10** after implantation. Such anti-migration features may include ridges **6** provided along the top surface **31** and/or bottom surface **33**. Additional anti-migration features may also include a pair of spike elements **7** disposed within the proximal region of the implant **10**, a pair of spike elements **8** disposed within the distal region of the implant **10**, and a pair of spike elements **9** disposed within the central region of the implant **10**. Spike elements **7**, **8**, **9** may extend from the top surface **31** and/or bottom surface **33** within the respective proximal, distal and central regions of the implant **10**. The spike elements **7**, **8**, **9** may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements **7**, **8**, **9** may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant **10** such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces **31**, **33** of the implant **10**. As best appreciated in FIG. **4**, the spike elements **7**, **8**, **9** may each comprise a unitary element extending through upper and lower surfaces **31**, **33**. Alternatively, each spike element **7**, **8**, **9** may comprise a shorter element which only extends through a single surface **31**, **33** (that is, does not extend through the entire height of the implant **10**). In any event, when the spike elements **7**, **8**, **9** are provided having radiodense characteristics and the implant **10** is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements **7**, **8**, **9** will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant **10** during implantation and/or the placement of the implant **10** after implantation.

The spinal fusion implant **10** has two large fusion apertures **2**, separated by a medial support **50**, extending in a vertical fashion through the top surface **31** and bottom surface **33**. The fusion apertures **2** function primarily as an avenue for bony fusion between adjacent vertebrae. The fusion apertures **2** may be provided in any of a variety of suitable shapes, including but not limited to the generally rectangular shape best viewed in FIG. **3**, or a generally circular, oblong and/or triangular shape or any combination thereof. The spinal fusion implant **10** may have a plurality of visualization apertures **4** which allow a clinician to make visual observations of the

degree of bony fusion un-obscured by the lateral side **14** to facilitate further diagnosis and treatment. The visualization apertures **4** may be provided in any of a variety of suitable shapes, including but not limited to the generally oblong shape best viewed in FIG. **4**, or a generally circular, rectangular and/or triangular shape or any combination thereof.

The spinal fusion implant **10** may be provided with any number of suitable features for engaging the insertion instrument **20** without departing from the scope of the present invention. As best viewed in FIGS. **4-6**, one engagement mechanism involves providing a threaded receiving aperture **12** in the proximal sidewall **22** of the spinal fusion implant **10** of the present invention. The threaded receiving aperture **12** is dimensioned to threadably receive a threaded connector **24** on the insertion instrument **20** (as will be described in greater detail below). The receiving aperture **12** extends inwardly from the proximal side **22** in a generally perpendicular fashion relative to the proximal side **22**. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture **12** may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular. In addition to the receiving aperture **12**, the spinal fusion implant **10** is preferably equipped with a pair of grooved purchase regions **60**, **61** extending generally horizontally from either side of the receiving aperture **12**. The grooved purchase regions **60**, **61** are dimensioned to receive corresponding distal head slots **62**, **63** on the insertion instrument **20** (as will be described in greater detail below), which collectively provide an enhanced engagement between the implant **10** and instrument **20**.

FIGS. **6-9** detail the exemplary insertion instrument **20** according to one embodiment of the invention. The exemplary insertion instrument **20** includes an elongate tubular element **28** and an inserter shaft **44**. The elongate tubular element **28** is constructed with a distal head **26** at its distal end, distal head ridges **62**, **63** on the distal end of the distal head **26**, a thumbwheel housing **38** at its proximal end and a handle **42** at its proximal end. The elongate tubular element **28** is generally cylindrical and of a length sufficient to allow the device to span from the surgical target site to a location sufficiently outside the patient's body so the handle **42** and thumbwheel housing **38** can be easily accessed by a clinician or a complimentary controlling device.

The elongate tubular element **28** is dimensioned to receive a spring **46** and the proximal end of the inserter shaft **44** into the inner bore **64** of the elongate tubular element **28**. The inserter shaft **44** is dimensioned such that the threaded connector **24** at the distal end of the inserter shaft **44** just protrudes past the distal head slots **62**, **63** to allow engagement with the receiving aperture **12** of the spinal fusion implant **10**. It should be appreciated by one skilled in the art that such a construction allows the inserter shaft **44** to be able to rotate freely within the elongate tubular element **28** while stabilized by a spring **46** to reduce any slidable play in the insertion instrument **20**.

The handle **42** is generally disposed at the proximal end of the insertion instrument **20**. The handle **42** is fixed to the thumbwheel housing **38** allowing easy handling by the clinician. Because the handle **42** is fixed the clinician has easy access to the thumbwheel **34** and can stably turn the thumbwheel **34** relative to the thumbwheel housing **38**. Additionally, the relative orientation of the thumbwheel housing **38** to the handle **42** orients the clinician with respect to the distal head **26** and distal head slot **62**. By way of example, the thumbwheel housing **38** holds a thumbwheel **34**, a set screw **32**, and a spacer **36**. The inserter shaft **44** is attached to the thumbwheel **34** and is freely rotatable with low friction due to the spacer **36**. One skilled in the art can appreciate myriad methods of assembling a housing similar to the above described.

FIG. **6** details the distal head ridge of the exemplary insertion instrument **20** coupled to the spinal fusion implant **10** through the purchase regions **60**, **61**. The distal head slots **62**, **63** are dimensioned to fit slidably into the purchase regions **60**, **61** with low friction to allow accurate engagement of the threaded connector **24** to the receiving aperture **12** of the spinal fusion implant **10**. In the presented embodiment, the outer dimension of the threaded connector **24** is smaller than the largest outer dimension of the distal head **26** and elongate tubular element **28**. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the spinal fusion implant **10** is chosen, the distal head slots **62**, **63** of the inserter shaft **44** are inserted into the purchase regions **60**, **61** of the spinal fusion implant **10**. At that time the spinal fusion implant **10** and insertion instrument **20** are slidably engaged with one another. Before the clinician can manipulate the combined spinal fusion implant **10** and insertion instrument **20**, they must be releasably secured together. In order to secure the spinal fusion implant **10** onto the threaded connector **24** of the inserter instrument **20**, the clinician employs the thumbwheel **34** to rotate the inserter shaft **44** and threaded connector **24**. The rotation of the threaded connector **24** will releasably engage the receiving aperture of the spinal fusion implant **10** and stabilize the insertion instrument **20** relative to the spinal fusion implant **10**.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel is created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space may be prepared via any number of well known preparation tools, including but not limited to kerrisons, rongeurs, pituitaries, and rasps. After preparation, the insertion instrument **20** is used to place a spinal fusion implant **10** into the prepared intervertebral space. Once the implant **10** is inserted into the prepared space, the implant **10** is released from the insertion instrument **20** by rotating the thumbwheel **34** to disengage the threaded connector **24** from the receiving aperture **12**. That motion removes the compressive force on the purchase regions **60**, **61** between the distal head **26** and the distal head ridges **62**, **63** of the spinal fusion implant **10** and allows the insertion instrument to be slidably removed from the implant **10**. After the threaded connector **24** is disengaged from the implant **10**, the insertion instrument **20** is removed from the working channel and the channel is closed. As previously mentioned, additional materials may be included in the procedure before, during or after the insertion of the spinal fusion implant **10** to aid the natural fusion of the targeted spinal level.

FIG. **10** illustrates a spinal fusion system **105** for performing spinal fusion between adjacent cervical vertebrae, including an exemplary spinal fusion implant **110** and an exemplary cervical insertion instrument **120** provided in accordance with the present invention. The spinal fusion implant **110** may comprise of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant **110** may be provided in any number of suitable sizes, such as, by way

of example only, a length ranging between 11 to 14 mm, a height ranging between 5 and 12 mm, and a width ranging from 14 and 16 mm.

As will be described in detail below, the cervical insertion instrument **120** is configured to releasably maintain the exemplary cervical fusion implant **110** in the proper orientation for insertion. The cervical fusion implant **110** may be simultaneously introduced into a disc space while locked within the cervical insertion instrument **120** and thereafter released. The exemplary cervical fusion implant **110**, having been deposited in the disc space, effects spinal fusion over time as the natural bone healing process integrates and binds the implant with the adjacent vertebral bodies. This fusion may be facilitated or augmented by introducing or positioning various materials in a space created within or adjacent to the cervical fusion implant **110**. Those materials may be introduced before, during, or after the insertion of the exemplary cervical fusion implant **110**. The additional material may include bone autograft harvested from the patient receiving the spinal fusion implant **10**, one or more additional bone allograft, bio-resorbables or xenograft implants, any number of non-bone implants, and any number of fusion promoting compounds such as bone morphogenic protein.

FIGS. **11-14** depict various embodiments of the exemplary cervical fusion implant **110**. Some common attributes are shared among the various embodiments. More specifically, each cervical fusion implant **110** has a top surface **31**, a bottom surface **33**, lateral sides **14**, a proximal side **22**, and a distal side **16**. In one embodiment, the top and bottom surfaces **31**, **33** are generally parallel. It can be appreciated by one skilled in the art that although the surfaces are generally parallel, that the top **31** and bottom **33** surfaces may be angled with respect to one another to match the natural curve of the spine (i.e. lordosis or kyphosis). By way of example, implants for the cervical or lumbar regions of the spine will have anterior height greater than the posterior height to match the natural lordosis in those regions. Inversely, the implants designed for implantation into the thoracic region will be manufactured with a posterior height greater than the anterior height to match the natural kyophosis in that region. Additionally, the angled surface can aid in overall fit within the vertebral disc space.

The cervical fusion implant **110** preferably includes two receiving apertures **12** which are centrally aligned on the proximal side **22**. The receiving apertures **12** extend inwardly from the proximal side **22** in a generally perpendicular fashion relative to the proximal side **22**. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture **12** may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular.

The exemplary cervical fusion implant **110** also preferably includes anti-migration features such as anti-migration teeth **6** along the top surface **31** and bottom surface **33**. Additional anti-migration features may include a plurality of proximal anti-migration spikes **68** and/or distal anti-migration spikes **70** integrated vertically through the cervical fusion implant **110**. The anti-migration features increase the friction between the cervical fusion implant **110** and the adjacent contacting surfaces of the vertebral bodies. That friction prohibits migration of the cervical fusion implant **110** during the propagation of natural bony fusion. It should be appreciated by one skilled in the art that such anti-migration teeth **6** can be oriented in any manner other than generally vertically (as shown) without departing from the scope of the present invention. Moreover, as described above, the spikes **68**, **70** may be constructed from any of a variety of radiopaque materials, including but not limited to a metal, ceramic, and/or polymer material. When the spike elements **68**, **70** are provided having such radiodense characteristics, and the implant **110** is manufactured from a radiolucent material (such as, by way of example only, PEEK and/or PEKK), the spike elements **68**, **70** will be readily observable under X-ray or fluoroscopy such that a surgeon may track the progress of the implant **110** during implantation and/or the placement of the implant **110** after implantation.

The cervical fusion implant **110** has one large fusion aperture **2**, extending in a vertical fashion through the top surface **31** and bottom surface **33** which will function primarily as the avenue for bony fusion between adjacent vertebrae. The cervical fusion implant **110** may have a plurality of visualization apertures **4** which can also serve as an avenue of bony fusion on the lateral sides **14** via cell migration or additional adjuvants. The visualization apertures **4** serve an additional function of allowing a clinician to make visual observations of the degree of bony fusion un-obscured by the lateral side **14** to facilitate further diagnosis and treatment.

FIG. **15** illustrates, by way of example, the orientation of the cervical fusion implant **110** prior to attachment to the cervical insertion instrument **120** by a clinician. One skilled in the art would appreciate that although the current embodiment shows a slidable engagement, various other methods of engagement are contemplated; such as, threadable or hooking features.

FIGS. **16-17** detail the tubular lock member **21** of the exemplary cervical inserter instrument **110**. The tubular lock member **21** includes a central bore **25** dimensioned to receive the proximal end of the elongate fork member **11** therein. The internal dimension of the central bore **25** is smaller than the largest freestanding outer dimension of the taper feature **19**. As a result, the portion of the elongate fork member **11** that may be received by the central bore **25** of the tubular lock member **21** is limited by interference between the distal end of the tubular lock member **21** and the taper feature **19** of the elongate fork member **11**. In the present embodiment, the outer dimension of the threaded feature **13** of the elongate fork member **11** is smaller than the largest outer dimension of the taper feature **19** on the elongate fork member **11**. A thread feature **23** (not shown) at the proximal end of the tubular lock member **21** is situated inside the central bore **25**. The thread feature **23** matches the thread feature **13** on the elongate fork member **11** so that they can be threadably attached to one another. To ease the rotation of the tubular lock member **21** by hand, two semi-circular wings **27** may be provided protruding laterally outward from either side of the tubular lock member **21**. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel is created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space would be prepared (via known instruments as described above). After preparation, the insertion instrument **120** is used to place a cervical fusion implant **110** into the prepared intervertebral space. Once the cervical fusion implant **110** is inserted into the prepared space, the implant **110** is released from the cervical insertion instrument **120** by retracting the tubular lock member **21** from the elongate fork member **11** by rotating the tubular lock member **21** with respect to the elongate fork member **11** in the opposite direction from that used to initially secure the implant **110**. That motion removes the compressive force on the purchase region **39** between the apertures **12** of the cer-

vical fusion implant **110** and allows the engagement features **17** to be slidably removed from the apertures **12**. After the engagement features **17** are disengaged from the cervical fusion implant **110**, the cervical inserter instrument **120** is removed from the working channel and the channel is closed. As previously mentioned, additional materials may be included in the procedure before, during or after the insertion of the cervical fusion implant **110** to aid the natural fusion of the targeted spinal level.

In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the cervical fusion implant **110** is chosen, the engagement features **17** of the elongate fork member **11** are inserted into the apertures **12** on the implant **110**. At that time the cervical fusion implant **110** and elongate fork member **11** are slidably engaged with one another. Before the clinician can manipulate the combined cervical fusion implant **110** and elongated fork member **11**, they must be releasably secured together. In order to secure the cervical fusion implant **110** onto the elongate fork member **11**, the clinician would next employ the tubular lock member **21**. The clinician would insert the proximal end of the elongate fork member **11** into the central bore **25** of the tubular lock member **21** at its distal end. The tubular lock member **21** would then be advanced over the elongate fork member **11** until the thread feature **13** of that member and the thread feature **23** of the tubular lock member **21** become engaged.

Once engaged, advancement of the tubular lock member requires rotation of the tubular lock member **21** with respect to the elongate fork member **11**. Preferably, after only a small amount of engagement of the thread features the distal end of the tubular lock member **21** would contact the taper feature **19** of the elongate fork member **11**. The tubular lock member **21** would be advanced creating greater interference as the distal end approaches the distal end of the taper feature **19** which has the larger outer dimension. The increasing interference would laterally displace the clamping arms **15** of the elongate fork member **11** towards each other. Since the engagement features **17** of the elongate fork member **11** were initially inserted into the apertures **12** of the exemplary cervical fusion implant **110**, the displacement of the clamping arms **15** would create a compressive force on the purchase region **39** separating the apertures **12** of the exemplary cervical fusion implant **110**. That compressive force allows a clinician to manipulate the system without the exemplary cervical fusion implant **110** becoming disengaged from the cervical inserter instrument **120**.

The enhanced visualization features of the implants **10**, **110** are explained in greater detail with reference to FIGS. **18-23**. FIG. **18** illustrates an implant **10** dimensioned particularly for use in a posterior approach (PLIF) having (by way of example only) a width ranging between 9 and 11 mm, a height ranging between 8 and 14 mm, and a length ranging between 25 and 30 mm. FIG. **19** illustrates the implant **10** of FIG. **18** from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements **7** and **8** (there is no central spike element **9** as with FIG. **1**) relative to the implant **10** and visualization apertures **4**. FIG. **20** illustrates an implant **10** dimensioned particularly for use in a lateral approach (XLIF™ by NuVasive) having (by way of example only) a width of approximately 18 mm, a height ranging between 8 and 16 mm, and a length ranging between 40 and 45 mm. FIG. **21** illustrates the implant **10** of FIG. **20** from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements **7**, **8**, **9** relative to the implant **10** and visualization apertures **4**. FIG. **22** illustrates an implant **110** dimensioned particularly for use in the cervical spine having (by way of example only) a width of approximately 11 mm, a height ranging between 5 and 12 mm, and a length of approximately 14 mm. FIG. **23** illustrates the implant **110** of FIG. **22** from a side perspective via as taken via X-ray or fluoroscopy techniques, clearly showing the location of the spike elements **66** relative to the implant **110** and visualization apertures **4**. In this fashion, a surgeon may easily track the progress of the implant **10**, **110** during implantation and/or after implantation by visualizing the spike elements **7**,**8**,**9** and **66**, respectively, under X-ray and/or fluoroscopy according to the present invention.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

For example, while described herein primarily with reference to the lumbar and cervical spinal surgery, it is to be readily appreciated that the spinal fusion implants of the present invention may be suitable for accomplishing fusion in the thoracic spine without departing from the scope of the present invention. Moreover, it is to be readily appreciated that the insertion tools described herein may be employed with implants of any number of suitable constructions, including but not limited to metal, ceramic, plastic or composite.

What is claimed is:

1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:

an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, wherein said longitudinal length is at least two and half times greater than said maximum lateral width;

at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and

at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three

radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

2. The spinal fusion implant of claim **1**, further including at least one receiving aperture position is said proximal wall.

3. The spinal fusion implant of claim **2**, wherein said receiving aperture is configured to releasably mate with an inserter tool.

4. The spinal fusion implant of claim **3**, wherein said receiving aperture comprises a threaded receiving aperture extending into said proximal wall and having a central axis generally parallel to said longitudinal length of said implant.

5. The spinal fusion implant of claim **4**, further comprising a pair of lateral grooves positioned in said proximal wall and extending laterally of said threaded receiving aperture.

6. The spinal fusion implant of claim **1**, further comprising a medial support extending between the first and second sidewalls.

7. The spinal fusion implant of claim **6**, wherein said medial support is positioned along said central region.

8. The spinal fusion implant of claim **1**, further including a second fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space.

9. The spinal fusion implant of claim **8**, wherein said second fusion aperture is separated from said first fusion aperture by a medial support.

10. The spinal fusion implant of claim **1**, wherein said anti-migration elements of said upper surface comprise a plurality of ridges.

11. The spinal fusion implant of claim **10**, wherein said plurality of ridges extend generally perpendicular to said longitudinal length.

12. The spinal fusion implant of claim **1**, wherein said anti-migration elements of said upper surface comprise spike elements.

13. The spinal fusion implant of claim **12**, wherein said spike elements protrude to pointed tips configured to engage said first vertebra.

14. The spinal fusion implant of claim **1**, wherein at least one of said three radiopaque markers comprises an elongate body extending generally perpendicular to said longitudinal length.

15. The spinal fusion implant of claim **14**, wherein aid elongate body of at least one of said three radiopaque markers is shorter than a height extending from said upper surface to said lower surface.

16. The spinal fusion implant of claim **1**, further comprising a fourth radiopaque marker situated within said implant, said fourth radiopaque marker positioned in said central region at a position spaced apart from said third radiopaque marker.

17. The spinal fusion implant of claim **1**, wherein said first radiopaque marker has an elongate body oriented generally perpendicular to said longitudinal length and extending entirely through a height of said distal wall, and wherein said second radiopaque marker has an elongate body oriented generally perpendicular to said longitudinal length and entirely through a height of said proximal wall.

18. The spinal fusion implant of claim **1**, wherein said maximum lateral width of said implant is approximately 18 mm.

19. The spinal fusion implant of claim **1**, wherein said radiolucent material comprises PEEK.

20. The spinal fusion implant of claim **1**, wherein said implant includes at least one visualization aperture extending through at least one of said first sidewall and said second sidewall.

21. The spinal fusion implant of claim **1**, wherein said upper and lower surfaces are generally parallel to one another.

22. The spinal fusion implant of claim **1**, wherein said upper and lower surfaces are generally angled relative to one another to approximately correspond to lordosis of a lumbar spine when said implant is positioned within the interbody space.

23. The spinal fusion implant of claim **1**, wherein said first fusion aperture is one of generally rectangular and generally oblong in shape.

24. The spinal fusion implant of claim **1**, wherein said maximum lateral width of said implant is greater than a lateral width of the distal end of said distal wall and is greater than a lateral width of the proximal end of said proximal wall.

25. The spinal fusion implant of claim **1**, wherein said implant has a height extending from said upper surface to said lower surface, wherein said maximum lateral width is greater than said height.

26. The spinal fusion implant of claim **1**, wherein said central region includes a maximum height of said implant extending from said upper surface to said lower surface, wherein said maximum height is greater than a height of said distal wall and is greater than a height of said proximal wall.

27. The spinal fusion implant of claim **1**, wherein the lateral aperture width of said first fusion aperture is more than two time greater than a lateral thickness of said first sidewall and is more than two time greater than a lateral thickness of said second sidewall.

28. The spinal fusion implant of claim **1**, further comprising an osteoinductive material positioned with said first fusion aperture.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 8,187,334 B2
APPLICATION NO.	: 13/079645
DATED	: May 29, 2012
INVENTOR(S)	: Matthew Curran and Mark Peterson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13, Line 46 (Claim 15), delete “aid” and insert -- said --, therefor.

Signed and Sealed this
Seventh Day of August, 2012

David J. Kappos
Director of the United States Patent and Trademark Office